CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 505A
Washington, DC

Monday, November 22, 2004
8:30 a.m.

Council Members

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DR. JAMES BERGERON
DR. RONALD CASTELLANOS
DR. PETER GRIMM
DR. REBECCA GAUGHAN
DR. CARLOS HAMILTON
DR. DENNIS IGLAR
DR. JOE W. JOHNSON
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Dr. MARCEL SALIVE, Director
Division of Medical & Surgical Services
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Public Witnesses

None

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MS. DANA TREVAS, Rapporteur

A G E N D A

Morning

Afternoon

Open Meeting

Dr. Rapp: Good morning. I would like to call the meeting to order. I am Michael Rapp. I'm Chairman of the Practicing Physicians Advisory Council. And this actually is our 50th meeting of the Council, I'm told, so it's an anniversary. In addition, of course, it's Thanksgiving week, so I appreciate all of the members of the Council and others that have come, spending some time at this important time of the year, helping our government improve the Medicare Program. I'd also like to thank the staff that has been diligently at work in preparation for this meeting, John Lanigan, Ken Simon, and Bernice Harper have spent most of the weekend working on this as well as other time, and so we appreciate all they've done to put things together. You'll see that the members of the Council are seated. You probably have a hard time figuring out how you're seated most of the time. But it's alphabetical. So that's how the members of the Council are seated. [Chatter] Welcome. The first item on the agenda will be Dr. Thomas Gustafson, who's the Deputy Director for Center for Medicare Management. He's going to give us some opening remarks. Mr. Herb Kuhn, who's the Director for the Medicare Management is not going to be able to be here with us today. In terms of how I'd like to conduct the deliberations and proceedings today; I would like to invite the members of the Council to make recommendations on the different topics as we go along. So what I'm going to do is, as you know, each particular subject, has a limited time for us to consider it. So perhaps, ten or so minutes before the end of the time we have allowed to discuss an item, I'm going to ask that we don't discuss that particular topic anymore and open it up for recommendations for the Council so we can get those as we go along. If we find we don't have any recommendations, you want to continue to ask questions or make comments, we can do that. But at least this way, we won't run into the problem of losing a few members toward the end of the day and their not being here for the deliberations of the recommendations. So is there anything that any member of the Council has before we get started? If not, Dr. Gustafson?

Dr. Gustafson: Thank you, Dr. Rapp. And I'm here to offer the welcome of the Agency to the Commission. Herb Kuhn, as Dr. Rapp just mentioned, is not available today. The hidden secret is he's off in Italy, taking a well-deserved break. And I am none the less pleased to be with you, the welcomed post-election Washington, we're all getting a fresh head of steam for the upcoming four years. And once consequence of course, for the re-election of President Bush is we preserve a degree of continuity as we go forward when leadership remains in place, and we don't have the disruption that might be attendant on a change of administration. So we want to take advantage of that and move forward in a variety of different ways. Since we met last, the Physician Rule has come out for the update for January first and I know there'll be discussion of a number of different aspects of that rule in the course of this meeting and we'd be very much interested in the observations of the members of Council have about the efforts that the agency put forth there. You'll see a number of your concerns are reflected, although not necessarily chapter and verse what you would have done had you been us. That having been said, I'm going to stop quickly because I really don't have too much more that would be a contribution to our forward movement. So let me turn the matter back over to Dr. Rapp.

Dr. Rapp: Thank you very much. The next person on the agenda is Dr. Kenneth Simon, who's the Executive Director for the Practicing Physician Advisory Council for Center for Medicare Management. He'll provide us with an update on the August 30th recommendations for the Council and the Centers for Medicare and Medicaid Service's responses. Thank you, Dr. Simon.

Dr. Simon: Good morning, again, to the Council members and welcome to today's meeting. Reviewing the minutes from the last meeting, which occurred in August, there were several recommendations made by the Council, which we will address today. Item D-1, the Council recommended that CMS announce its intention in the Final Rule for 2005 Physician Fee Schedule to use its administrative authority to removed drugs from the SGR calculation, retroactive to the base year, the period from April 1st, 1996 through March 31st, 1997. Mr. Steve

Philips, the Director of the Division of Practitioner Services for CMM provided the response. CMS believes that the Physician Payment System should be structured to control costs and achieve predictable and stable changes to Medicare's rates while being equitable to physicians. Administrative changes affecting the SGR would have significant long-term cost implications, but would not have an impact on the update for 2006, or the subsequent few years. Therefore, without a statutory change, there will be a reduction the Physician's Fee Schedule rates for 2006 and subsequent years.

For agenda item D-2, PPAC supports the agency's attempts to reduce fraud and abuse in the prescription of durable medical equipment. The Council recommends the proposed rule requirement for a face-to-face physician-patient visit for prescription of durable medical equipment be limited only to prescription of power-operated vehicles. Section 1832 A1E of the Social Security Act, as added by Section 302 A2 of the Medicare Modernization Act requires the Secretary to establish clinical conditions of coverage standards for items of durable medical equipment. The statute requires the Secretary to establish types or classes of covered items that require a face-to-face examination of the covered individual by a physician or specified practitioner. Due to the proximate time frame of publication of the Physician Fee Schedule Final Rule, and the extensive number of public comments received, we will address all public comments in a future *Federal Register* document.

Agenda item D-3: PPAC recommends the Welcome to Medicare examination be reimbursed commensurate with the level of service provided, rather than limit it to the compensation for a level 3 office visit, as currently specified. The initial preventive physical examination is intended to target selected modifiable risk factors and secondary prevention opportunities shown by evidence to improve the health and welfare of the beneficiary, and it's less focused on a comprehensive physical examination, compared to the typical service providing in accordance with CPT-Code 99397, which reflects one of the preventive medicine services. We equated the resources anticipated to this service to the existing new office or other out-patient

visit in this instance, CPT-Code 99203. The RUC survey data for this code shows 53 physicians minutes, including pre-service time, intra-service time, and post-service time with 51 minutes of staff time. We believe the initial preventive physical examination will reflect these time approximations and will be looking at the data and consulting with the medical community after initial experience with this new benefit, to determine if this payment has been valued appropriately.

For Item D-4, PPAC recommends the specifics of the Welcome to Medicare examination, except as required by statute, be left to the discretion of the examining physician, or other provider. CMS believes that the statutory parenthetical language (including measurement of height, weight, and blood pressure and an electro cardiogram) recognizes that other services could be contained within the initial preventive physical exam benefit. We use the authority under Section 1871 A of the Social Security Act, through the Rule Making Process to provide clarity as to the specific services that are to be included under the new benefit. The intent of our language in the Final Rule for the actual physical examination portion of the benefit is to lead to the discretion of the physician or other qualified non-physician practitioner whether to perform commonly utilized physical examination measures, for example, such as oscultation [not in medical dictionary] of the heart or lungs on a patient if needed. We have specified in the Final Rule that additional physical examination measures may be performed if deemed appropriate, based on the issues identified by the physician or the clinician in the review of the service elements identified in the exam. We do state that the practitioner perform in the preventive examination, follow current clinical standards and those guidelines may include evidence-based guidelines.

Item F-1. The Council recommends the competitive bidding process include medicines administered in physicians' offices for all specialties, not just oncology. CMS intends to proceed through the full notice and comment rule making in 2005, with respect to the Medicare Part B Drug Competitive bidding program, including the scope of drugs included.

For Item F-2. The Council recommends CMS involve PPAC in the development of the Competitive Bidding process. Response: The CMS always values the input of the Practicing Physicians Advisory Council and will continue to do so for Drug Competitive Bidding.

For Agenda Item G. The Council recommends CMS explore all resources available from both government and private industry sources, to collect the most recent up-to-date and accurate data for making relative value units, geographic practice cost index, and Medicare Economic Index determinations. The law requires the Secretary to develop an index to be used in the updating of physician payments. Since this development in the 1970s, the responsibility for the Medicare Economic Index has remained in the Office of the Actuary in the Centers for Medicare and Medicaid Services. While the index was originally developed in the 1970s, the Office of the Actuary periodically revises and rebases the MEI to reflect more recent costs and practice patterns. We are always exploring the various data sources from private industry and government that are available for updating the MEI, both the cost weights and the price proxies in the MEI. The index was rebased to a 2000 base year for the 2004 update. Details of this can be found in the November 7th, 2003 *Federal Register*. The main source of data for the latest rebasing came from the patient care physician survey published by the AMA. This data was then supplemented with other data sources, such as the Bureau for Labor Statistics, ECI data, and the Bureau of Economic Analysis IO data. The rebasing was completing using the most current data available from the AMA at the time of rebasing, calendar year 2000 data. Though we continue to evaluate all available data sources, we have not found any private industry or other data that meet our criteria and are more recent than the latest data from the AMA. In addition, the price proxies used in the MEI are the most current data available. As has been our policy, we will continue to monitor the MEI to ensure it adequately reflects the cost of practice faced by physicians.

For average sales price, Agenda Item H-1: The Council recommends CMS proceed with caution in implementing the Average Sales Price rates. CMS should make broad use of any discretionary authority it might have to make exceptions to, revisions to, or delays in ASP rates.

If CMS does not believe it has authority to delay these changes until it has complete and reliable data, they should ask Congress for such authority. Section 1847 A of the Social Security Act specifies that the market based average sales price payment system for Medicare Part B drugs is effective January 1, 2005. Section 1847 A does not provide CMS with the authority to increase the ASP payment rates. We believe manufacturers understand the requirements of the law with respect to calculating and reporting the ASP data that will be used to set the payments effective January 1, 2005. As we gain experience under the ASP payment system, we will assess its overall use, and work with Congress to determine and implement changes as deemed appropriate.

Agenda Item H-2. The Council recommends CMS publish the complete list of covered drugs prices on the CMS website by early September 2004 so physicians can make comments before the September 24, 2004 deadline for comments on the Proposed Rule. In addition, drug payment rates published in the November 2004 Final Rule should be considered interim rates that are subject to further refinement as more data are gathered on payment changes. CMS published the available data from the second quarter of 2004 as soon as possible in conjunction with the Final Rule. We welcome public input on these drug prices, which will be updated quarterly. Section 1847 A of the Social Security Act does not provide CMS with the authority to increase ASP payment rates.

For Agenda Item H-3. The Council recommends CMS establish a system for monitoring how access to drugs is affected by the new ASP methodology. CMS should continually evaluate whether a response to lower drug acquisition and administration payments 1. physicians can afford to purchase, and administer the drugs needed for appropriate treatment of their patients, 2. physicians have to lay off medical or administrative staff, 3. physicians have to close satellite offices or discontinue or limit the types of treatment they offer, 4. patients have to travel further to get medical treatment because physicians in their area can no longer afford to provide it, 5. patients have higher out of pocket costs because they seek treatment at hospital-based facilities, alternative medical facilities, such as hospital out-patient departments, have the proper medical

infrastructure in place including drug inventory, adequate medical staff, medical equipment and facilities to provide quality medical treatment, especially in rural areas and finally, alternative medical facilities are available to absorb the additional patient load caused by fewer physician offices providing treatment. The CMS response is: CMS expects the combination of increased drug administration payments and the implement of the new market-based drug pricing system will result in continued access to high quality cancer care. We will be monitoring access closely and are ready to work with Congress to address systematic access issues that may arise.

For Agenda Item N: The Council recommends CMS give serious consideration to coding and relative value changes suggested by the agency's RUC committee and the AMA CPT Editorial Panel and that suggested changes remain exempt from budget neutrality, as specified in the Medicare Modernization Act. CMS has worked with the CPT Editorial Panel and the AMA RUC Committee since the inception of the Medicare Physician Fee Schedule. CMS has been working closely with the CPT Editorial Panel and the AMA RUC Committee in the development of CPT-Codes and payment rates for each of the codes related to drug administration services. As specified in the Medicare Modernization Act, these services will be exempt from budget neutrality from the years 2005 to 2006. CMS will implement temporary codes to allow payment for administration services in 2005. The new CPT-Codes will become active January 1, 2006.

Agenda Item N-2: PPAC recommend CMS immediately publish the list of areas by zip code in which the 5% incentive payment is available to physicians and specify those specialties in short supply, including primary care. Regarding the publication of the list of eligible areas for the new 5% bonus payment, CMS posted the list of physician scarcity areas on the CMS website on October 1, 2004. We also plan to publish which was done, the list in the Physician Fee Schedule Final Rule.

At the last meeting, several of the presenters raised questions by which they sought assistance from the Council. The first request relates to the Council was asked for suggestions concerning CMS in the Chronic Care Improvement Program. In the Council members had the

following suggestions regarding the Chronic Care Improvement Program: 1. CMS provide information on the website regarding the program; 2. the program should have sufficient patient self-care as one of its features; 3. primary care physicians should serve out front as team members, and 4. the investigators involved with the program should not have the ability to approve or disapprove physicians services. The last meeting Agenda Item L, the Council was queried on how they could assist in testing the PECOS web application. The Council responded by indicating the assignment of NPI numbers is scheduled to begin testing in May, 2005, and there were several members of the Council who agreed to help test the system. An additional request was: How could the Council help with educating physicians on the NPI and its significance to them. And the Council responded by suggesting that CMS seek to publicize the NPI requirement through state licensing boards. And the final request, was that the name, social security number, and date of birth must be consistent with the SSA information for enrollment and NPI actions to process. How can the Council help us inform the community? At that time, the Council did not provide any specific recommendations.

Dr. Rapp, that concludes the comments from the last Update.

Dr. Rapp: I thank you, Dr. Simon. Are there any questions or, from the Council for Dr. Simon? Dr. McAneny?

Dr. McAneny: Does one of the requests that we had made was that in looking at how we understand the rebasing of the MEI and looking at the using all resources, there are actually two things I have questions on. One is it would be helpful to hear some very specifics about why the market basket was felt to be the appropriate mechanism for hospitals, yet the MEI for physicians. Why not just use the market basket updates for physicians and hospitals since we are both using the same resources and competing for the same personnel equipment, etc., and the second one was the question of whether or not for office rent rates, whether or not there was any look at what the OIG uses when they decide that someone is not doing a fair market value transaction. So

those two questions: one is why not use what the OIG uses to figure out fair market values for office rents, and then why the difference between market basket and MEI?

Dr. Gustafson: Let me offer just a quick comment on at least the last point you raised. Fair market rents, as investigated by the Office of the Inspector General are done on a highly targeted basis, looking at conditions in a local market, very local market, relative to perhaps the purchase or sale of a particular office building, things of that sort. It's equivalent to looking for comparables when you are buying or selling a house. It is not a systematic nationwide data source that we could tap to use for this purpose. On the first point, I believe the answer probably lies along an issue relating the various weights that are put on the various inputs in these two indices, but I confess to not be familiar with the detail of them. And perhaps what would be appropriate if we could seek some input from the Office of the Actuary, perhaps provide some information in writing to members of the Council to resolve that question and we can check further on the other question as well.

Dr. Rapp: Did you have anything else to add, Dr. Simon?

Dr. Simon: [no]

Dr. Rapp: Dr. Castellanos, then Dr. Bergeron?

Dr. Castellanos: I think one of last meeting, why doesn't CMS use the same data source OIG for the professional liability insurance? And I think I provided you with that information at the last meeting.

Dr. Simon: CMS uses a variety of data sources based on specified criteria to help provide accurate information to enable it provide up to current up to the date information as it pertains to malpractice premiums. I think part of the issue as well has been addressed in the Final Rule, though it's not totally inclusive of identifying all of the data sources that it uses. I think that one of the things we can do for the Council, however, perhaps in writing for the next meeting, is to identify the requirements that CMS has in place to determine which data sources are used and are not used in calculated the NPI.

Dr. Bergeron: We as dermatologists are presently getting into the dispensing of medications through our office, such as all the biologicals coming on the market. And we've been trying to set some parameters, insurance department comes and says, "Well, Dr. Bergeron, you got to pay this amount of money for this particular medication." What's the mark-up if you will? Is it comparable to the jewelry store, is it comparable to the bar? The liquor store, etc.,etc. And this is, we're virginal at this. Oncologists, rheumatologists have been at this for a while. So when we say competitive bidding, if indeed, we buy this biological A for $100, and we mark it up according to what it costs to administer it, the nursing staff, the administration staff, etc., etc., and we submit this to a third party payee, whether it be Medicare or some private insurance providers, what parameters, or any, or should we consult rather than at the present time, our oncologists, our rheumatologists who've been doing this for quite a while, hematologists? Are there any parameters out there to set a specific price, competitively, if you will, that would be a fair and equitable for our time and efforts, where do we find this data? Are the rheumatologists and oncologists we should consult, use their parameters, their factors? Competitive bidding. Exactly explain what you mean by competitive bidding. If one company has Raptilers [?], one of the biologicals we use, well, there's nothing comparable to it. So how am I supposed to get competitive bidding unless I go with an entirely different drug, such as Amevie [?], which we're giving in the office. It's cloudy for us as dermatologists; this is virginal territory for us.

Dr. Simon: I think in the through our rulemaking process in 2005, we will be more expansive in terms of the methodology that will be used for the competitive bidding process as well as providing opportunity for specialty groups and physicians in particular, such as yourself, to raise those questions, as we attempt to explain how that process will be devised and provide the mechanisms in place so that people will understand the system that will be used to determine how that system will function. So I think that if we stay tuned through our rulemaking process, early next year, CMS will provide more information in that regard.

Dr. Bergeron: Because we were told by the companies that submit a figure. It can get shot down, you might get reimbursed and that's a little like flying by the seat of our pants. If I come in and tell a patient we got to submit $2,000 and we get back $900, they'll come back with you were charging too much in the first place. We had that happen. So now we just fly, you know.

Dr. Simon: I think that through our proposed rule making process, it will provide a vehicle where we will be able to articulate what that process will be, and again, explain where the methodology will go and also gain input from the community so that we can refine it for the end of 2005.

Dr. Bergeron: Thank you.

Dr. McAneny: Could you expand on that—and don't go to the oncologists—we're as confused as everybody else, especially with the competitive visiting part. But can you give a time table of when you expect to have the proposed rule making out for competitive biddings, and when do you expect to have the various companies, or whoever is going to reply to this, establishing their standards for 2005 since this is the law we're going to be living on for 2006? It would be handy to know earlier rather than later.

Dr. Simon: We'll ask Mr. Thompson to respond.

Dr. Thompson: You have an inquiry here. A little bit of a preview for some information we're going to have later but I think that the way that the process will work is that as Dr. Simon mentioned, hopefully in the early spring of 2005, we'll be going out with the proposed rule. In that proposed rule will contain the policy surrounding the competitive bidding, which is going to be implemented in January 1, 2006. There will be a comment period. We'll obviously take those comments, make any necessary modifications, go out with the final rule, then at that point, we'll be able to start the bidding process. And then obviously we'll go through the bid process. Bids will accept from all the different vendors. Do our evaluations, get those out, and then physicians will obviously be given a choice in the fall between continuing to go under the ASP plus 6 methodology, buy the drugs themselves, or go with the vendor.

Dr. Rapp: Thank you. Any other comments or questions? Dr. Bergeron?

Dr. Bergeron: Dr. Thompson, why are we always reactive rather than proactive. Here I have a span. These biologicals are there. We are keeping up with the cutting edges, and yet on the economic side—medically speaking, we're there on the cutting edges. The best laser this side of heaven, the best biologicals. Yet in administering to these patients of ours, economically we're in the dark. So is there any possibilities that we look on the horizon of what's coming in, what's in the practicing physician's office, and have certain parameters that we can deal with, rather than wait until January 05 or January 06, right now we have about 40 patients in our office, as we speak, receiving these biologicals.

Mr. Thompson: Understood. Obviously the earlier we have the information the better, without question. And ideally we'd be sitting here right now, we'd know precisely what the vendors were going to be able to propose for January 1, 06, but I would submit if you asked them right now, even if we had the apparatus up and running, it wouldn't be clear that they in fact would know today what they'll be billing over a year, what the possibility will be in terms of the competitive bidding. I'm not sure the vendors themselves would know or even aside from competitive bidding, could someone tell me what the price of any drug's going to be January 1, 2006. I'm not sure anybody has the ability to do that this far in advance.

Dr. Bergeron: As we speak, right now, we have one patient $11,000, we have because there was no way we could determine specifically and get parameters, and as we say in south Louisiana, the individual insurance reneged on the deal.

Dr. Thompson: I guess in terms of where we stand—

Dr. Bergeron: Because the patient is being treated presently. Not 2006.

Dr. Thompson: I think in terms of obviously what Medicare pays for 2004 is a known quantity. So as of today, you know what the Medicare reimbursement is, and again, that's statutory. That was based on the locked in AWP amount. So I think in terms of where we stand right now, it's a known fact what Medicare would reimburse for any drug. I think in terms of '05,

again, we've put out the second quarter prices. So while it's not the second quarter of '04, the ASP data, and obviously we have a new payment system in '05 and we'll have those data—they're in-house now, contractors, working on it. Hopefully you'll have those up for early December for use January 1, and that is to a certain extent, that time lag, the data doesn't even come in to until the end of October, October 30th, because by law they have 30 days beyond the end of the reporting period and we're hoping to turn that around in 4 weeks, which is a pretty tall order. So there's not much faster we can go in terms of getting the precise '05 rates. So I guess if you could just expand a little bit. You have the '04 rates now. We have the '05 rates—at least if you want to project them, based on what we've published based on the second quarter, which I think is roughly 98, 99% of all the Medicare drug expenditures, and then in '06, we'll be going through the notice and comment rule making. So I guess if you could just maybe repeat the question in terms of what piece of information would you like to have today that you don't have?

Dr. Bergeron: Specifically, what do we charge? What fees do we submit to third party carriers if we have no "competitive bidding." Is Medicare—I'll tell you, what you could consult the other side of the house, Medicaid, they have these figures for us.

Dr. Thompson: When you see "these figures," that's the part I'm kind of struggling with.

Dr. Bergeron: The figures are what we charge for the drug, what's our mark-up, what's a fair mark-up to administer, and what we get reimbursed? In other words, before then—excuse me—we saw a patient. We didn't, we didn't purchase any drugs. I never been in the retail business. This is retail business and you have to educate me. I'm a dermatologist, board certified, I'm a physician, but come into retailing, it's a whole new ballgame for us. So if we're going to have patients under the Medicare guidelines, it would be nice when a Medicare patient comes in with a horrible psoriatic erythrodermic, yes! There's this new biological. They come in on the Internet. I want this. Well, I don't know how—well, you going to purchase it? Yes, but the drug, I'll tell you one thing, the drug company bills us 30, 60, 90, and if 90 days not paid will turn over to the Credit Bureau. So what I'm getting at is, you come in this morning as a Medicare patient. I

want this drug. This is the best. And I know it's the best for you. I don't know what to charge you. I don't know what bill to submit to Medicare as we speak at the present time. So in other words, you want me to withhold the biological 'til January '06 on this Medicare patient until you give me all the parameters, the charges, which submit charges, etc. What's a fair mark-up?

Dr. Thompson: And maybe this is a, this is a question we could maybe follow up on offline. If you give me a drug, I can tell you how much we're paying now. How much the Medicare reimbursement will be.

Dr. Bergeron: But will you come back and say, "Did you get a competitive bid?"

Dr. Thompson: The competitive bidding system is not effective until January 1, 2006, so right now, if you tell me a drug, I can tell you what the price is. For right now, a patient walks in, I can tell you how much Medicare is going to reimburse you for that. And then very shortly, if you ask me in early December, and you give me another drug, I can tell you what Medicare will be reimbursing January 1, 2005. I guess beyond that, in terms of if you're saying where can you get the drug, or what's the purchase price for the drug, I think that there is obviously a number of different drug distributors and wholesalers out there. Perhaps others can shop around between those in terms of getting the best acquisition costs. But Medicare is not in the business of purchasing the drug. We can tell you what we're going to reimburse for it, but to a certain extent I don't know if your medical society helps with information about how to purchase drugs and prudently, but there's no competitive bidding aspect to anything today or in 2005, with respect to treating the patients. That's really an '06 issue. But I can tell you today, and maybe we can follow up, but if you tell me a drug, I can tell you what we're paying for it, or I can contact your carrier or we can work with the system so you wouldn't have to call me all the time, but there are ways to figure out—they're on our website, or we can get your staff, tell them where it is on our website. They can download it. We update up quarterly. So the information's out there at least in terms of what the Medicare payments are.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: Since he's opened up this discussion, can we continue it now or should we delay it?

Dr. Rapp: Well, you can continue it for four minutes and 45 seconds.

Dr. Castellanos: I'll be glad to give you some J-Codes. I'm starting patients on treatment now which is 2004, but these treatment plans will continue into 2005, and I can tell you at this time on AWP, it's a wash. I can tell you on the ASP plus 6% based on the figures you gave me, I have losses. So what do I do January 1st? Do I stop giving this drug? What happens there, and I can give you the J-Codes if you would like, right now.

Dr. Thompson: Sure. If you have the payment amounts, I would probably just be giving you back the same, but I would like the information.

Dr. Castellanos: I'd be more than glad to give you that on intravesical therapies for bladder cancer. Because I'm going to be seeing these patients and the oncologists have the same problems. They're going to be starting treatment based on 2004 reimbursements, and then a month later, we really haven't hit the final figures yet, you're expecting me to continue these treatments and take a financial loss. And I'm a small business man. I understand your pressures with MMA, you had a tremendous crunch. But the private physician also has a tremendous financial crunch to figure out what the heck we're going to do.

Dr. Rapp: So are you saying that you can't purchase the drug for what the reimbursement is—

Dr. Castellanos: I can say we can purchase the drugs based on ASP on the second quarter and I'm taking a loss based on my acquisition costs, and I will be glad to show you my receipts on what I'm paying for the drug.

Dr. Thompson: I think we'll be, I think consistently is that the ASP plus 6% is statutory, so we don't have the regulatory authority. So if you look at the ASP system in the MMA, it does not give the Secretary the authority to raise the price. That section of the law. So from a

regulatory, administrative standpoint, the statute says that the drug price is the Average Sales Price plus 6%.

Dr. Castellanos: I understand that. But the bottom line, when the tide hits the road is what do I tell my patients January 1st that I can no longer afford to give them this drug because I loose money—what do I tell my patients? And where do I send them for that treatment? I haven't got any good answers. And we have what, 6, 7 weeks to figure that out.

Dr. Rapp: So, are you saying you cannot purchase particular drugs for the Average Wholesale Price plus 6%?

Dr. Castellanos: That's correct. And I can show you the receipts and the data, and I'm sure the oncologists can show you the same. Not all our drugs. And I guess we're going into another issue, but when we get into 206 with competitive bidding/competitive acquisition and ASP, it would be nice to be able to have a hybrid, so the ones that I can't afford to give, I can buy that drug and be assured that my patient will get that treatment, yet on ASP plus 6%, if there's any profit, that the physician service and company can still make some profit. It would be nice to have a hybrid system based but on MMA, I don't think, at least statutorily that's written in the law.

Dr. Rapp: OK, I'd like to draw this to a close in order to stay on time, so if that's all right with you, we will, thank you, Mr. Thompson, we will see you again. Thank you, Dr. Simon for that information. And the next item on the agenda is the PRIT update. We have Dr. William Rogers who's the Medical Office to the Administrator, Dr. McClellan. And he will provide us with an update on the Physicians Regulatory Issue Team, otherwise known as the PRIT.

Dr. Rogers: Thanks, Mike.

Dr. Rapp: Otherwise known as the Cartoon Purveyor.

Dr. Rogers: The cartoon purveyor. I only have one this report, I'm sorry to report. But you know I provide access to my cartoon library free of charge to all PPAC members as an added benefit of serving on this august committee. Before I get started, I just want to amplify a little on

what Don was saying, because I think Dr. Bergeron's point about this horizon scanning and being ready for new technology is a very good point. And we have now a committee for technology and innovation, which is composed of members at the highest level of management at CMS and the main function of this committee is to make sure that we're ready when new technology is approved, with payment rates, with coverage rules, and things like that so that there isn't a delay and I think what CMS did with drug [?] is sort of an example of the way we should be ready for new technology when the FDA approves it. So this CTI meets regularly and has a very important function that it's fulfilling, so we are aware of the need to be ready for new technology.

First slide: What's new? I wanted to introduce Jackie Whitley, who just joined the PRIT team. Jackie worked for Mark Hatfield for a decade, for four years and then worked for a decade after that at the Federation. She knows, it seems, just about everybody in health care in the United States and we are thrilled to have her on board. She is going to help us to reach out to some smaller organizations and state medical societies that I haven't done a very good job of reaching out to, and that's her primary charge with us and so we're very excited to have her on board. And feel that this is going to help us at being more effective at making individual physicians and small groups realize that they have a voice here at CMS. [chatter]

This is the only cartoon, and Mike's blocked the caption, but it says the physician's obviously talking to his wife or his girlfriend, and he says, "By all means, dear, buy it you really want it, we'll find the money for it somehow." The patient's looking a little bit anxious up there.

I'm going to go quickly through the PRIT issues that you might be interested in. A couple of really easy sort of issues that we were asked to deal with this year, late in the year. One was a PAP screening problem. Physicians were—a patient would come into a physician's office and ask to have another screening PAP smear done when the patient had already met their statutory limit of one every two years. And the physician would say to the patient, Medicare's not going to cover this. They'd say, I know, but I read an article or whatever. I want to have another one done. They'd say, OK, just as long that you'll have to understand that you'll have to pay. The patient

would fill out an ABN. Physician would bill Medicare as they were supposed to. Medicare would pay the physician. The physician would refund the money back to Medicare, then would bill the patient. The problem was, the patient would get information that said that Medicare had paid for the service. And then when they got a bill from the physician then they would think they were being double-billed, because they'd be unaware that the physician had refunded the money to Medicare. And so what we're doing now is going to have a final meeting about the use of a different modifier to address this physician can bill the patient at the time of the initial service and you won't have to go through this refunding process and everything. And it's really just a clarification of the use of the modifier.

The second thing was an issue that was of concern to a lot of people, but particularly to Dr. Grimm. And the problem was that a CPT-Code had been used for a long time to bill for the radio-isotope implants in brachytherapy and that CPT-Code disappeared in the 2005 CPT book, which left them with no way to bill for a pretty expensive product. And so Medicare was actually poised and ready to react to make this [interference] to allow that to happen. But it was nice to see how Medicare was able to fix this problem.

E&M services. I spoke to the gastroenterologists on Saturday in Chicago, and I'm still recovering from the wounds. There's a lot of concern amongst gastroenterologists. They believe that there is not money in the payment for the screening colonoscopy to pay for the very reasonable services which are required to make certain that a patient can safely undergo procedural sedation. And their concern that there isn't any money included in the payment for screening colonoscopy, and they believe, many of them, that every patient who has a screening colonoscopy should have also paid for an E&M-Code before the screening colonoscopy. And there's been a lot of communication between CMS and the gastroenterologists for a number of years over this issue. And so we're just keeping it up there for discussion. But the big issue is whether there is some payment in the payment for screening colonoscopy for a small amount of preprocedure service. And until we further define that, which we're working on now, it's going to

be difficult to say what really the right thing to do on this is. Clearly I mean there are some patients who are very ill, who have a number of [pill?] morbidities and it would be appropriate to see them in the office a week before the screening colonoscopy to assess them and be sure they're ready for the procedures.

Ordering of POVs is something that we'll discuss a little bit later.

Cardiac Rehab Supervision. This is actually sort of on hold until we get the OIG report. But the issue is that many smaller hospitals have routinely had the emergency physician who's usually right down the hall from where the cardiac rehab is occurring as the supervising physician. And we have said some things that suggest that maybe that's not entirely kosher. It's unclear. And we can't really clarify it until the OIG publishes its report on cardiac rehab which we expect any day. But it sort of holds up the process until we know how they're going to write the report. But it's a real problem, particularly for some rural hospitals that are concerned about whether their programs are following the letter of the law. This is also an issue that's being considered by the CTI.

Security of anesthesia carts is a big issue for anesthesiologists, because our conditions of participation are somewhat at variance with joint commission and state requirements about when carts have to be locked and they don't have to be locked. And there are some safety issues here because the anesthesiologists believe that a locked cart can be a problem if a patient suddenly needs something unexpectedly and it's difficult to access the drugs and supplies on the cart. But this is a conditions of participation, one of four PRIT issues that are in the conditions of participation which are in the final, final, final stages of [development?].

Also, history and physicals by podiatrists. This has been an issue that's been with the PRIT as long as I've been with the PRIT.

Reenrollment. This has not changed. And we're actually going to move this over to old issues. But I think by my next slide, when I talk about enrollment, which is really a great story, I think this issue we are very aware of and we're not going to do anything on reenrollment until we

are sure we can do it right. And I'm confident of that. I think that the enrollment group really has physicians' interests foremost and forefront.

Mental health treatment limitation has been a very difficult issue. We're still having discussions about when it should be applied, when it shouldn't be applied.

Use of macros in teaching documentation. We're talking to the AAMC and other groups. The concern here is on the one hand, with electronic medical records, macros are normal part of the way you do your documentation and so many teaching physicians say, when the resident's documentation is just absolutely everything that I could have written and more, and I really have nothing to add, why isn't it OK for me to just say, teaching physician macro, and have the computer or the person in Michigan or the person in India type, "I was present during the key components of the procedures. I agree with the resident's note signed, so and so." On the other hand, there are physicians and people who are concerned about quality documentation are concerned that teaching positions might use this excessively and not make sure that the residents now really did comply with all the CMS requirements and also give the information that might be required by a follow up physician or whatever. So the concern of AAMC is primarily that this macro might be overused. And that's a very reasonable concern. So we're in discussion about how exactly to word guidance about the use of macros. But it's obviously something that we have to weigh in on because with the growth of the use of EHRs, this is not an issue that's going to go away.

We've been very focused on provider enrollment, and this is a happy graph here. This looks at the backlog of patients waiting for provider numbers, and as you can see, last month, we actually crossed the baseline. We have fewer people waiting for provider numbers now than we did pre-PECOS. And this is a testimonial to the hard work of the Provider Enrollment Group and also to many unsung heroes at the carrier level who've been working overtime and working weekends to get this taken care of. But I think now PECOS is where we want it to be in terms of its reliability. And this doesn't mean that every carrier has dropped below the baseline, and we're

very aware of that. We're still working with individual carriers who haven't succeeded quite as much, but nationally, I think this is a problem that's been resolved.

Post-Anesthesia Reports is really and has been settled, because on our website there's a letter than you can link to, which says that it's OK for another anesthesiologist in the group to do the report, but we're still waiting for the conditions of participation to finally resolve this.

Verbal Orders. Anesthesia Billing Issues has to do with when an anesthetist starts a case and an anesthesiologist finishes the case and we're still optimistic that we'll be able to come up with a policy that both organizations are happy with, and that's sort of what we're working on right now.

And I'm not going to even mention the chemo-therapy codes issue because far wiser people than I are going to be discussing this later on but it has been an issue that we've been watching and trying to be helpful with.

So to finish up, I've been traveling a lot. I was in Chicago on Saturday, talking to the gastroenterologists and spoke to the American Association of Osteopathic Colleges on Friday and I'll be at the AMA meeting on the 5th. And really trying to make sure that individual physicians and small groups feel that we're concerned about their issues and that we are interested in resolving those issues. We're excited about Jackie helping us to reach physicians that we haven't been successful at reaching so far and with that, I'm open to questions, or issues or concerns.

Dr. Rapp: And questions for Dr. Rogers? Dr. McAneny?

Dr. McAneny: One is a question, just a clarification. Did I understand you right, Bill, to say that the re-enrollment is on hold until everybody's certain it can be done right?

Dr. Rogers: Well, my understanding last time I talked about this with our experts on it was that we were not going to begin to require re-enrollment until we were sure that we had a robust and user friendly internet interface which would allow the process to be done painlessly.

Dr. McAneny: Excellent. And I think we'd all be willing to be guinea pigs to try to re-enroll and see if it can be done on line. It seems it would be nice to have it so that if you make an

error it doesn't say, guess what I'm thinking, figure out what the error is. And then make you start all over and resubmit. So that's wonderful. And that's very good news. The other question I had was on the use of the macros, it just seems strange to me that we will take university professors and trust them with people's lives and trust them to teach the future doctors, but we won't trust them to know when to use a macro in documentation. And it seems just sort of the wrong attitude to me that these are our professors and our teachers and the folks who are going to teach us all how to do things right and we don't trust them to use a macro or not appropriately?

Dr. Rogers: I think it's a good point. I've always said that I think good physicians are good physicians despite our regulations and bad physicians will be bad physicians despite our regulations. We fool ourselves if we think that the bad physicians are aware that there's a regulation that says X, Y, or Z, but on the other hand, there's probably nothing more important once you've gotten your treatment plan implemented than the documentation you do so that the doctor that follows you knows what you did and so that the malpractice attorneys have something to read. And we don't want to do anything to sort of diminish the quality of those records. So I think that's probably the counter balancing concern.

Dr. Simon: I don't think the issue is whether CMS understands when attending physicians realize the appropriateness or not of when to use the macro system. The real point is that there area variety of electronic medical record systems on the marketplace which had varying degrees of sophistication. Some of those systems do not enable, or don't have the capability of allowing a reviewer to distinguish care from one patient to the next. So that the system would not indicate that the care has actually been appropriately tailored by the physician to the uninitiated observer. So CMS has been working with the AAMC recognizing that this is a landscape that currently is under review and will continue to change and once there is a baseline of electronic medical records systems out there that have that sophistication where care can be identified and demonstrated to be tailored appropriately so to the care of the patient, where it actually protects the attending physician when he or she provides care to the patient, then I think

the AAMC and CMS will work in concert to create the policy changes that will be of benefit to all that are involved.

Dr. Grimm: This is just a comment about format. Bill, I like the way you present this information to us. It's very easy to understand the issue. It's very understandable what's being done. Ken, I'd like to encourage you and the other folks that deal with the issues, with these other recommendations that we have to use a similar format and have it to us available before we get to this meeting so that we can assess what's being said. It's very difficult to follow if somebody's reading something and then think about what's being said and then respond appropriately. And this is a very nice way to show what you've done in a chronological way and I appreciate, Bill, your organization of this. Very easy to understand.

Dr. Gaughan: Well, first I want to thank Dr. Rogers for the PECOS improving, since Kansas is one of the worst states.

Dr. Rogers: I get no credit for that.

Dr. Gaughan: So I want to thank you. And then I want to make a recommendation.

Dr. Rapp: OK.

Dr. Gaughan: PPAC recommends that CMS be applauded for approving additional funding for all carriers that requested to hire part-time staff to clear the backlog of enrollment. And I will comment that that is the major thing our carriers were telling us you want us to clear the enrollment, but you won't give us any money or personnel. So I would like to applaud CMS.

Dr. Rapp: Is there a second to that?

??: Second.

Dr. Gaughan: I hate to be nice, but. . .

Dr. Rapp: Yeah, I was concerned somebody might think that was out of order.

Dr. Gaughan: I know.

Dr. Rapp: So, Dana, do you want to read that back?

Ms. Trevas: PPAC recommends that CMS be applauded for approving the additional funding for all carriers who requested funding for part-time staff to clear the backlog of enrollment.

Dr. Gaughan: For physician enrollment.

Ms. Trevas: Physician enrollment.

Dr. Rapp: Any discussion? All in favor?

[Ays]

Dr. Rapp: That carries. Anything else for Dr. Rogers?

Dr. Simon: I think as a point of information to the Council, one of the points that Bill raised in regards to the Council for technology, the CTI committee is that it would also be important for the Council to recognize that part of the usual operating mechanisms within CMS is that when new services, procedures or technologies are presented to the agency and those groups, manufactures or specialty groups submit their application process, requesting coverage for new devices, procedures, technologies, our discussion at the end of my update was pertaining to drugs, as articulated by Dr. Bergeron. But for technology and devices, if those devices and so forth are deemed to be covered under 1862 A1A by the Social Security Act, then we usually will create either a C-Code or a G-Code and provide coverage for those services, making them available to the physicians so that they not only can provide the service to the patients, but more importantly be reimbursed for those services when they provide them to patients on a quarterly basis. So those new technologies are addressed in a real time frame and the payment, the ability to have a code in place for it and the coverage is done expeditiously.

Dr. Rapp: Anything else? If not, thank you Bill, for introducing your new staff member, Ms. Jackie Whitley, and we are now at the time that we're going to have a brief break. We are a bit ahead of schedule, so the next item on the agenda is the Physician Fee Schedule Rule, which we're going to talk about at 10:00. So let's come back at 9:45 instead and begin that discussion then.

Dr. Rapp: OK, we'll resume the meeting now. The next item on the agenda is the 2005 Physician Fee Schedule Final Rule. As always, there is tremendous interest in the Final Rule of the 2005 Physician Fee Schedule, and the presenters will be four staff members from the Centers for Medicare Management. First of all, Don Thompson, Acting Deputy Director, Hospital & Ambulatory Policy Group, is that right? Steve Phillips, Director of Division of Practitioner Services, Marc Hartstein, Senior Advisor, and Dr. Edith Hambrick, Medical Officer, Hospital & Ambulatory Policy Group. The areas that they will be covering today will be the scope, payment, and impact of separate provision relative to EKG other services, codes, and additional Final Rule changes, and we'll hear about a one-year demonstration project also that's been included in the Final Rule. So who's going to start, Mr. Thompson?

Mr. Thompson: Actually, Mr. Phillips will start.

Mr. Phillips: Thank you. I appreciate the opportunity to come here this morning and present the changes that we implemented in the 2005 Physician Fee Schedule Final Rule which was published in the *Federal Register* November 15th, and as we presented to the Council in August, when the proposed rule was published, the Final Rule contains many important new changes to the Medicare Program, which we're going to cover. The key ones this morning, and basically our presentation is segmented. First we will focus on the Welcome to Medicare Benefit, malpractice RVU update, the five-year review of work relative values and some of the other miscellaneous issues in the rule. And Dr. Hambrick and myself will present this first segment and then we will focus more specifically on changes to payments for drugs and drug administration. And Don Thompson and Marc Hartstein will cover those sections. Moving to the Welcome to Medicare benefit, we received many comments on this benefit in response to the proposed rule. Generally, the comments were aggregated into four key areas related to the benefit. The scope of the examination, the appropriateness of the payment that was proposed, the comments recommending that we allow a separate provision of the electro-cardiogram aspect of the visit, and also comments on our proposal to limit the provision of additional evaluation management

services on the same day as the Welcome to Medicare benefit was provided. I realize that you'll be receiving a more complete briefing on the scope of the benefit this afternoon, so this morning we're going to focus on the latter three aspects, the payment issues that we addressed in the Final Rule. The first one, appropriate payment. Many commenters on the Proposed Rule believe the payment that was in the Proposed Rule would be insufficient. They characterized, for example, the benefit as being labor-intensive and requested that for example, we use the existing CPT-Codes for preventive services rather than creating a new G-Code. We examined that comment and basically the preventive services prescribed by existing CPT-Codes 99381 through 99397 are not covered by Medicare. And so that created problems with that comment, suggestion. We believe however that the physician staff time is associated with existing E&M-Code 99203 for an office visit with a new patient should closely approximate the resources we use to provide the Welcome to Medicare visit and as we show here on the slide, there are currently in CPT-Code 99203, there are 53 minutes of physician time and 51 minutes of office staff time. However, as we indicated in the Final Rule, as we proceed and physicians gain experience with providing the new service, we believe we will be better able to assess the appropriateness of this payment level.

The second issue under the Welcome to Medicare visit is comments that we received regarding the provision of the ECG. Many commenters expressed concern that not all physicians or non-physician practitioners have the equipment and capability to provide an electrocardiogram in their office or clinic. In the Proposed Rule, we proposed just a single G-Code for the entire service, including the ECG. We also received questions about whether an ECG must be performed in cases where a diagnostic ECG was performed in a recent visit. Investigating with our Office of General Counsel, this question, we came to the conclusion that the statute pretty clearly states that the ECG is part of the new benefit, and therefore, we don't have the authority to allow it to be excluded from the rest of the Welcome to Medicare visit. However, we did amend the policy in the Final Rule to recognize that there are many practitioners who may want to refer patients elsewhere for the ECG and interpretation and to accommodate these situations, we

created separate new G-Codes to allow the ECG portion of the benefit to be billed separately, either by the same practitioner, who provides the other portions of the visit, or by another provider by arrangement with the primary physician or non-physician practitioner.

This slide presents the new G-Codes that were published in the Final Rule in association with the new benefit. In the Final Rule, we indicated that in circumstances where the patient is referred outside for the ECG, that we expect the results to be including in the medical record at the primary care provider's part of the visit. If the complete ECG is provided at the same time, as the rest of the Welcome to Medicare visit by the same physician, both GO-344 and GO-366 should be reported on the claim for the Welcome to Medicare visit.

The final aspect of this benefit that I wanted to cover relates to the proposal to limit the provision of additional services on the same day as the Welcome to Medicare visit. Originally, out of concern about paying twice for overlapping services, we proposed to limit the level of an allowable medically necessary Evaluation & Management visit on the same day as the Welcome to Medicare visit to a level two E&M visit for new office patients. Commenters wrote that many Medicare beneficiaries come with multiple chronic problems that often necessitate immediate evaluation and management, equivalent to a level three or four visit. In response in the Final Rule, we removed the proposed restriction. However, we indicated services provided as part of the Wecome to Medicare visit should not be included in the determination of the appropriate level of the same day subsequent service so basically the overlapping services should not be counted twice and paid for twice.

Next, I want to talk about the update to the Malpractice RVUs. Yeah?

Dr. McAneny: One of my questions on this is what will happen if one of the factors in that laundry list of requirements is missed by the physician. Suppose the physician does not have an EKG machine in his office or her office and says, OK, you will go get this at such and such a place and the patient doesn't do it. It does happen that we tell patients to do stuff and they don't do it. So if they don't do that, has the physician just donated their time on everything else? If they

miss one factor, will the physician still get paid? Suppose then they forgot to ask about depression, or they didn't assess home safety, will they still get paid for that? And then the other question is why an EKG at all? The US Preventative Services Task Force did not say that there's any value to a standard screening EKG, yet we're going to be paying a huge amount of money, which I'm worried will also trigger volume and intensity questions and trigger the SGR cap for a service that while patients may feel like they got something for it because they put all those wires on their chest, really isn't going to do much?

Dr. Phillips: OK, I in response to the second question, and again these might be questions that would be useful to raise this afternoon when I think Dr. Salive from the Office of Clinical Standards & Quality is here to talk about the scope of the benefit—

Dr. Rapp: We're going to spend 45 minutes this afternoon on the new Medicare preventive benefits and the Welcome to Medicare exam, so. . . Go ahead and respond to the question and we'll cover this in more detail.

Dr. Phillips: Right. Just to point out that the bottom line answer is that the statute required that the ECG be part of the benefit, so it didn't really leave CMS with a lot of discretion. As far as the merits of that, that might be something for this afternoon's discussion.

On your first question about if the ECG is referred outside, again, the statute is pretty clear that that has to be part of the benefit, so we don't feel that we have a lot of discretion to waive that if it's not performed. We're looking at an issue in instructions in terms of the billing for the benefit, but believe that it has to occur as part of the entire scope of the benefit in order to pay for it.

Dr. Rapp: Thank you.

Dr. Phillips: Then, I mentioned, we also included in the Final Rule, the update to the malpractice RVUs as part of our 5-year review of the Malpractice RVUs. Commenters requested in response to the Proposed Rule that we remove the utilization from assistance at surgery, from the calculation of the malpractice RVUs. Pointing to the fact that this utilization lowers the

average risk associated with surgical services. And in response, we adopted this comment. We removed the assistant at surgery data from the calculation for the Final Rule, resulting in higher RVUs for some surgical specialties. We also received comments suggesting that we adopt a methodology that would only count for the dominant specialty providing the service. And we responded to this comment that we believe that a methodology utilizing risk factors associated with all of the specialties that provide a service, weighted appropriately to account for the overall proportion at the time the service was provided by each specialty is the more equitable approach to establishing malpractice RVUs in order to accurately reflect the malpractice costs associated with providing the service on average. However, in conclusion on that point as well as just the entire discussion on malpractice RVUs, we indicated that we do intend to continue working with the AMA's relative value update committee and identified some specific points that we think will merit further discussion. The dominant specialty approach is one. We are open to continuing to discuss that, although, made clear our current position at least in the response to that comment in the Final Rule. Also to work identify the most current nationally representative professional liability insurance data. We actually had a discussion just last week with the representatives of the RUC on potentially accessing some data may be more up to date that we could begin to look at as an alternative to the data that was used to the calculations in the Final Rule. And also to better identify low volume data that may just be aberrant within a particular specialty, and some rules for identifying aberrant data, as opposed to just low volume specialties within a particular service.

With that, I'm going to turn it over to Dr. Hambrick to talk about the five-year review of work and the other issues.

Dr. Hambrick: Good morning. It's my great pleasure. I'm sure that you are all eagerly looking forward to the announcement of the third five-year review cycle. I'm sure that there will be many comments that we will receive in response to that announcement. We are requesting comments on potentially misvalued work RUVs for all services in the calendar year 2005 Physician Fee Schedule. We also will identify codes, especially high volume codes across

specialties that are valued as being performed in the in-patient setting, but that are now predominantly performed on an out-patient setting. And those codes that were not reviewed by the RUC. In addition to internal review and analysis, we propose to share the comments we receive on all work RVUs with the RUC, which currently makes recommendations to CMS on the assignments of RVUs to new and revised CPT-Codes.

I just want to talk briefly about some other Final Rule changes. You will note that we updated the geographic practice cost indices for physician work and practice expense, some of which we've alluded to earlier today. We also revised the payment rules for low osmolar contrast material. We revised the requirements for supervision by therapists of therapy assistance. In addition, certain ESRD services were added to the list of Medicare Tele-Health services. We announced new G-Codes, some of which Mark will discuss later, but I'd just like to draw your attention to a few. One was for the vascular mapping for hemo-dialysis access. Second code that we established was for bone marrow aspiration when performing bone marrow biopsy through the same incision on the same date of service. You might recall that that was an issue that had been brought forward a couple of years ago. And thirdly, we arranged a G-Code for hospice consultation provided by hospice medical director or physician employee, as stated in the statute. We also provided an update to the Physician Fee Schedule of 1.5% as mandated by Congress. And just to let you know, the provision concerning clinical conditions for coverage of DME was dropped from the Final Rule.

I believe that Don Thompson will take over now and discuss the issues.

Dr. O'Shea: Concerning the revised requirements concerning adjunct to services. I going to pose that question please. Would you have any information on what codes are specifically affected. I know that there's more going to come out later, but there's still much query about how a physician can use adjunct medical personnel and still get paid for it. There are still many questions. Do you have any specific codes that were going to be affected by this.

Dr. Hambrick: Those are the services for the 2 to 3 visits or 4 or more visits, so those services, those codes as relate to hemodialysis with those, and I think they're listed in the rule. I don't have them right here with me, but those are the services.

Dr. O'Shea: OK, but actually it was different than just the hemodialysis. What I'm talking about is adjunct to services, something that had come out at our last meeting, specifically for physician assistance, physical therapists and what they could provide. And there are other medically trained personnel in office being supervised by the physician, also giving medical benefit in the form of services to the patient, and again, these were called adjunct to services. I just wanted to know if you had any specific codes that you were looking at to limit.

Dr. Hambrick: I don't think there were any specific codes, I think it went to the benefit, so if there are certain services, the physical therapy services, the TO therapy services, those traditional services that normally would have had to have a certain type of provider providing them like a therapist or someone who has all the qualifications for therapist except for licensure. Is that the provision that you're talking about?

Dr. O'Shea: It is. And I think that Mr. [?] spoke to this at the last open forum. I think that it was a change from law that was written before. It got more specific but didn't seem to include many other types of providers that are still within the office, or actually helping with home visits and things like that. Again, any specific codes that were—

Dr. Phillips: As Dr. Hambrick indicated, there wasn't focus on specific codes. Basically the statute refers to therapy provided incident to physicians services. We are as indicated in the Final Rule, developing specific instructions on implementing this provision that we indicated in the Rule we anticipate would probably be out on or about March 1st of next year to actually provide more specific guidance on implementing that. That should help answer some of the questions.

Dr. Simon: And if focuses basically on the services that pertain to occupational therapy, physical therapy, and that of a speech language pathologist. And in the rule, it indicated that the state requirements would be in place except for state licensure.

Dr. O'Shea: I'll look for the on the further edification because some of our physicians were concerned that it was more far reaching than just that. But we'll look for it in March first. Thanks.

Dr. Rapp: So we're up to the. . .

Dr. Thompson: Drug and drug administration. Next slide. Kind of broke this into three pieces. One is the payment for the drug itself on the average sales price methodology and I'll be speaking about that. And then the drug administration; the codes and the payments, and Marc Hartstein will be discussing those and then the one-year demonstration project for 2005 that was for oncology. That is also in the Final Rule and we'll be discussing that as well.

With respect to the drug prices. The average sales price system will be paying 106% of the average sales price as reported to CMS by the drug manufacturers quarterly. The prices that will be used for the Final Rule are prices that are from the third quarter of 2004 and they were reported to us at the end of October, as I mentioned earlier, we're turning those around hopefully to have those up in early December and that will be the price that will be in effect January 1, 2005. Those fees will be updated quarterly, so in the second quarter of 2005, the payments will be based on data that reported to us from the fourth quarter of 2005. And that data will be reported to us by January 30th, according to the law. In conjunction with the Final Rule, we also put up on our website information from the second quarter. And that was covering 373 drugs and about a little over 98% of the total drug spend other than the drugs that don't have HCPCS-Codes.

The quarterly pricing updates, early December, and those first rates will be effect for the first quarter and then after that, they'll be updated quarterly as the pricing changes and as the manufacturers report that data to us. And I'm sure there may be some questions on that, but I was

going to let Marc talk a little bit about the drug administration unless anybody wanted to stop at this point and speak to the drug prices themselves before we moved on. OK.

Mr. Hartstein: Before I begin my remarks, I just want to let folks know I've had the opportunity to come and speak to this panel on a number of occasion as a senior adviser in the Hospital and Ambulatory Policy Group, and I am currently transitioning to some new responsibilities as the Acting Deputy Director of the Division of Acute Care, the division that does the in-patient hospital perspective payment system. I don't know if this panel ever hears from the in-patient hospital folks, but if not, then I guess you won't be hearing from me for at least a year. So I just want to say that it's been my honor and pleasure to come and speak to this panel on the many complex and difficult issues related to Physician Fee Schedule services and drugs that I've had the opportunity to speak with you about.

I'll go through some of the provisions of the Final Rule related to drug administration. These were some very big changes, obviously, for people who administer drugs. We worked very closely with the medical community to make these changes and with their support, although we realize that these are some very significant changes that will be occurring in these codes and that it will be a major change to have physicians bill for drug administration services.

Just to give you a little background, in the Medicare Modernization Act, the statute required us to make a number of changes to drug administration for 2004 and then some additional changes for 2005. For 2004, those changes required us to use a survey that was a survey of practice expenses that was conducted by the American Society of Clinical Oncology, in addition to some other changes which had the effect of permanently increasing payments for the drug administration code by a weighted average of more than 110%. In addition to those permanent changes, for drug administration, the statute also required additional temporary changes of 32% for 2004 only and then that 32% additional payment becomes 3% for 2005 only. Then in 2006, what we have referred to as the transitional adjustment will no longer be made and

payments will be at the traditional methodologies where we multiply the relative value units by the conversion factor.

The Medicare Modernization Act was enacted very late in 2004, signed by the President on December 8th. We put our Physician Fee Schedule rule in the *Federal Register* on January 7th, and we had made it available to the public on December 31st through the office of the *Federal Register*. So obviously there was some very late changes in payments for 2004. In addition, the statute required the Secretary to evaluate the drug administration codes using our existing processes. So because the statute was enacted so late in 2004, we weren't able to undertake this evaluation, and because it said that we should use our existing processes, we felt it was giving us direction to work with the medical community through the current procedural terminology, or CPT Panel as well as the Relative Value Update Committee. These are two groups that we work with closely in establishing codes and payment amounts for all Physician Fee Schedule services, not just drug administration.

The statute not only required us to use our existing processes, but also required us to undertake this review promptly. So we felt that to undertake this kind of review in a year, although it seems like a long time, for changes as significant, as complex as these changes, we felt that actually it was a short time frame. We are very grateful to the CPT Editorial Panel for establishing a drug administration work group in January of 2004. The drug administration work group met a number of times by conference call. They had a public meeting in June in Washington, D.C. where they allowed interested members of the public to come and make a presentation on the issues of concern to them about the drug administration codes. And we felt that the process was very open to listening to concerns and comments about all of the services associated, all of the drug administration services and related services.

The Drug Administration Work Group made recommendations to the full CPT Editorial Panel in August. The CPT recommended coding changes for 2005 to CMS. The CPT process was actually closed for 2005 so they were not able to incorporate the coding recommendations into

the 2005 CPT book. CMS is very reluctant to adopt G-Codes and we try to work as closely as we can with the CPT Panel wherever possible. And only try to establish G-Codes where there's some strong policy or statutory reason to do so. We felt that these changes for important to adopt in 2006 and the CPT Editorial Panel agreed with our decision to adopt G-Codes temporarily in 2005 until these permanent CPT-Codes could be adopted into the 2006 CPT System.

Because the recommendations from the CPT Panel came to the RUC, in September they needed some time to evaluate the codes and develop resource inputs for those, as well as recommendations on the physician work values. Very late in September, the RUC had a meeting that actually went into early October where they evaluated the codes and forwarded recommendations to us on work and the practice expense associated with all of the new drug administration codes in early October. For the Final Rule, we used the month of October to adopt temporary G-Codes in place of the CPT-Codes that I referred to before, as well as to develop the payment amounts in relative values for these new drug administration codes. As I said before, CMS's current plan is to retire these G-Codes in 2006 when they are first incorporated into CPT.

Just to outline some of the major changes that were made in coding for drug administration, they established what we view as essentially three different types of codes. They established codes for hydration, codes for non-chemotherapy injections and infusions, and then for chemotherapy administration, they expanded the definition of chemotherapy administration to go beyond antineoplastic drugs. So chemotherapy administration as defined by the CPT to include non-radionucleid antineoplastic drugs, antineoplastics agents for the treatment of non-cancer diagnoses, and monoclonal anti-bodies, and other biologic response modifiers.

In addition, the expansion of the definition of chemotherapy: A number of physicians who provided input to the CPT Panel had indicated they didn't feel the cancer-non-cancer distinction between these drugs was necessarily relevant in the current environment, because they felt that some of the drugs that are administered for non-cancer diagnoses, in particular mono-clonal antibodies, was the one most commonly used as an example, Remicade, for the treatment

of rheumatoid arthritis, that these drugs had some of the same risks associated and required monitoring of the patient and so forth that were similar to what would occur with chemotherapy drugs that are administered to treat patients with cancer, and so they felt since there were similar resources associated with the administration of some of these additional drugs, that the definition of chemotherapy should be expanded to include other than antineoplastic drugs.

Some other issues that were raised by sometimes in the cancer community and sometimes by other physicians, that needed to be addressed and the panel established specific codes for was additional sequential infusions. It's common, I understand, in chemotherapy that a patient will be administered more than one drug in a session. Under the old codes, we had a single code for first hour of infusion and then a single code for each additional hour of infusion. The initial code for the first hour of infusion was used for the first drug administered and the subsequent hour infusion codes were used for each additional hour of infusion, whether or not it was the first hour of a second drug or third drug infused or whether it was just the subsequent hour of a drug that was already being infused.

There were also some concerns that if two non-chemotherapy drugs were administered concurrently, there was really no additional payment for the infusion of the second drug that was administered concurrently. So now a separate code has been established that would allow the physician to also get paid for the administration of the second drug administered concurrently with the first drug.

And then there was only one code for drugs administered by intravenous push for both chemotherapy and non-chemotherapy. There was a feeling that there were additional resources associated with the second drug that was administered by IV push and there should be an additional code that recognizes the specific resources associated with the second drug administered by IV push and the CPT Panel recommendations will recognize that and they did recommend that we establish second codes for those as well. Another issue that was raised to us during the comment period as well as an issue that we felt needed to be considered: Currently, in

2004, Medicare does not make separate payment for injections when the injections are provided on the same day as an office visit or any other Physician Fee Schedule service. The payments for the injection are going to be bundled into payments for the office visit. The payments for the injections are now substantially higher. They were increased from eight to eighteen dollars and it was our feeling that these services had sufficient resources involved with them that they should be separately in addition to other physician fee schedule services that are provided on the same day as an injection. This is a provision that affects not only oncologists, rheumatologists and other physicians, that administer a lot of drugs, but it will also affect payments to family practitioners, internists, and others who frequently provide injections. In addition, before I move on to these other changes, I do want to say that Medicare pays for vaccine administration as well for the Medicare covered flu vaccines, hepatitis, and pneumococcal and in looking at the CPT recommendations, we realized that there were a lot of, large differences between the way our methodologies were resulting in payments for vaccine administration and therapeutic injections. And in looking at this, we felt that the resource cost associated with these different types of injection services were very similar so we decided to merge the data between the injections and the vaccine administrations and pay the same amount for all three. So Medicare currently is paying about $8 for the administration of a flu vaccine, will also be paying about $18 for that. So that's a substantial increase in payments for administering a flu vaccine.

One of the issues that was brought to the CPT Panel that got a lot of attention was that patients who were administered these drugs will sometimes have adverse reactions to the drugs. And there was a feeling among many presented to the panel that there should be distinct codes that physicians can bill when a patient is in an office setting and has an adverse reaction to the administration of a drug or to the drug itself. The CPT Panel did not create codes for the management of adverse reactions, but felt that there were existing codes that were already in place that the physician could bill and our Physician Fee Schedule Final Rule as well as some

other correspondence that we've had, clarifies that physicians can bill for these services and we will clarify it further in additional instructions that will be coming out in the near future.

Just to mention what some of these additional coding opportunities are, or existing coding opportunities are, the physician can bill a visit in addition to chemotherapy or another drug administration. This is currently the case and we've clarified that in our Physician Fee Schedule Rule. If the patient has an adverse reaction, the physician can bill a higher level visit based on the total interaction with the patient, in the event the patient is seen before and after chemotherapy. If the services are of sufficient length, it's possible for the physician to bill a prolonged services Evaluation & Management code and in the even that the adverse reaction is so severe, it is possible that the physician could bill in the office setting for critical care services.

As I said when I began this presentation, there were substantial increases in payments for drug administration under the MMA and then of course there are some additional coding changes that will occur in 2005. What I'm presenting here are the changes in payments without the transition, just to show you how much payment is increasing from 2002 to 2005 in the absence of the temporary adjustments that will happen in 2004 and 2005. So for instance, if you look at the 2004 payment, the payment for a therapeutic or diagnostic injection, which is currently coded under procedure code 90782, a CPT-Code. In 2005 will be coded under a G-Code, G0351. In 2002, we paid almost $4 for that service, in 2005, we'll be about $18.57 for that service. And just to clarify, the 2004 payment is not actually $18.67. That's what the payment would be in the absence of the 32% increase in payment that applies for 2004 only. Also, so the payment in 2004 is actually 32% higher than the $18.67. Similarly, for 2005, the $18.57 will actually be higher than the amount shown here. It will be 3% higher. These are national average amounts.

The reason I'm showing it this way is because I just want to show what the payments are, the permanent increases in payments as a result of all of the coding and RVU changes in absence of the temporary changes for '04 and '05. Just to cover a couple of different services, we did provide a more detailed list of CPT-Codes and G-Codes in the Physician Fee Schedule Rule, and

we did provide a lot of narrative in the rule that will provide guidance to physicians on how the old codes map to the new codes, that we hope will be very helpful to physicians in coding, beginning in 2005. And as I said before, we will have some additional instructions that will provide more detail to physicians, recognizing that these are substantial changes in coding, and that physicians will need some guidance on how to do the coding.

Procedure Code 96400, which in CPT is a chemotherapy injection, that code will actually be replaced by two different codes. One code for a hormonal antineoplastic injection under G-Code G0356. We paid about $5.07 for 96400 in 2002. In 2005, without the 3% add on, we will be about $35.62, so that's about a 603% increase for the injection of a hormonal antineoplastic. Just to give you an idea on another code, 96408, which is an IV chemotherapy push. It's new code will be G0357, so that's the initial IV push. We paid $35.11 for that code in 2002. We'll pay $122.03 in 2005. The code below it, G0358 is the IV push for each additional drug. We actually are paying for the second drug pushed in 2004 under procedure code 96408. Since CPT established a specific code for that additional push, we will use that code to recognize the specific resources associated with the additional drug administered by IV push, and then similarly, I also show procedure code 96410 with G0359. 96410 is the chemotherapy infusion. Below that, you'll see procedure code G0359 a second time. That's because procedure code 90780 which was a non-chemotherapy infusion in 2004, is possible that codes that were previously billed under 90780 will now be billed under G0359 and then of course the payment amounts for the codes under the CPT-Codes in 2002 and then the respective G-Codes in 2005 are shown there as well as some of the additional codes.

And so those are a highlight of some of the highest volume drug administration services that are billed to Medicare and how their payments are changing as a result of the MMA and then the coding and relative value changes recommended to us by the CPT Editorial Panel and the Relative Value Update Committee.

Dr. Grimm: Is this analysis available for all of the codes? Or did you just do these for us as just an example.

Mr. Hartstein: I provided these just as an example for you. There is a table in the *Federal Register* that lists the old code and the new code and their descriptors, without the payment amounts, of all of the drug administration codes. But it would be a simple matter for me to supply a table that includes the payment amounts as well for all of the codes to the Panel, and I'd be happy to do that through Dr. Simon.

Dr. Grimm: That would be great. Thank you.

Dr. Castellanos: I have a lot of questions concerning your presentations. One is just say a PPAC recommendation concerning malpractice RVUs. We discussed this briefly earlier and I don't think we need to continue that discussion. I'd like to make a proposal that PPAC recommends that CMS specifically identify all data sources for determining the update for professional liability RVUs.

Dr. Rapp: Could you hold that for one second until—I'd like to take a number of those at once?

Dr. Castellanos: OK. Another question that Steve brought up when you talked about pricing; one of the issues we have in urology is that of least cost alternative policies. As you know, the intent in Congress was to let market pressures and forces determine the price of ASP. This morning, Ken Simon, in answering a lot of the recommendations that we made at our last PPAC meeting, Ken specifically mentioned that he was going to let marketplace drug price affect the cost of drugs. We have a policy in the past called least cost alternative policy, and this is really a difficult situation, because in a lot of states across the country, the carriers have had trouble implementing LCAs, and urologists have had a lot of overpayment letters from different carriers, specifically Missouri, Oklahoma, New Mexico, Puerto Rico, Utah, and Idaho and I think LCA really creates an unlevel playing field. It's not the intent of Congress; it wasn't the intent that Ken mentioned this morning, letting market pressures do this. By doing this, it significantly

affects the payment on two urology drugs, specifically Lupron and Zoladex. I would like to make a recommendation concerning that, but should I do that at a later date?

Dr. Rapp: Well, in about 5 or 10 minutes.

Dr. Castellanos: OK. And my third point is in your discussion and your presentation you talked about this one-year demonstration project and there was no really—

Mr. Hartstein: That's coming up.

Dr. Castellanos: OK, great.

Dr. Rapp: Do you want to let him do the one-year demonstration project?

Dr. McAneny: I just have a question. Will the secondary payers going to recognize these G-Codes?

Mr. Hartstein: This is a comment that's been made to us frequently. It's actually a comment that came to us in the context of the G-Codes we established last year for the monthly capitation for patients who have end-stage renal disease. I'll ask my colleagues to help me on this. My understanding, under the HIPAA Rules the supplemental insurers and other private payers are obligated—that the HCPCS level 2 system is by definition, HIPAA-compliant, and they have to be able to accept those codes, but that we don't have an obligation to pay them for, or they don't have an obligation to pay for those G-Codes, so that it's possible that Medicare will pay for the G-Codes, those that are active and recognizable codes on the Medicare system. But that the physician may then have to bill the supplemental insurer a second time. Although these are issues that we are trying to make easier for physicians.

Dr. McAneny: And the follow-up question is this is similar to what Dr. Bergeron was asking earlier. If you have a patient who on January 1st needs a specific drug, the drug price that comes out December 15th reimburses lower than what you can purchase that drug for January 1st. Then will there be any mechanism or help from CMS to either let us know where in the country one might purchase such a drug at such a price if one can't get it locally, or any mechanism to perhaps retrospectively fix the ASP price back to the first of that quarter if you find that you

cannot get that drug. Because letting a patient wait from January 1st to the beginning of the second quarter, when it's a drug they need is unacceptable. Yet, physicians are not really going to be willing to eat the difference in what they can purchase the drug for and what the ASP provides. While the new infusional codes are very helpful, they don't make up that difference for a set of specific drugs.

Dr. Thompson: I think those are excellent points, and we've raised these with ASCO, and ASCO has committed to, as you know, they did a survey, and in that survey they found that there was quite a lot of variation with respect to the drug acquisition cost, and interesting enough, also found that practice size was not a determinant. That that wasn't an issue of large practices getting better prices than small practices. So they have committed to us that they are, on that specific issue, working to try to help physicians identify lower cost drug suppliers. So I guess one of my suggestions would be to contact ASCO and work with them and see what activities they're doing. Our understanding is that they're actively looking to [?] this exact issue for January 1.

Dr. McAneny: That helps me, but not Dr. Bergeron.

Dr. Thompson: Understood, but my question would be, if ASCO can do it, why can't other physician specialty groups assist in helping their members to the extent that there's variation in drug prices, help their members identify high quality suppliers and be prudent purchasers. You're seeing this variation. So that would, I think as we've sat down, we've had that same question about this drug pricing and what can we do to help. And it does appear, at least in the oncology, and I would assume as also for other specialties, they are interested in helping their membership identify these lower cost suppliers.

Dr. McAneny: But CMS is not going to do any sort of a physician hotline, or any information gathering independent of the specialty societies, that say physicians are unable, that rheumatologists cannot purchase a given drug or that neurologists can't get their Minazantro [?] or can't get all of these drugs at this price and help with the patient who needs that drug on January 2nd.

Dr. Thomson: Well, I guess in our mind, the actual specialty societies are better positioned. In other words, the membership is actually purchasing the drug and there are some portions of the membership that are actually, it appears, acquiring the drug at lower prices. So we would be even one further step removed than the specialty society, which can work directly with their membership to identify these lower cost high quality suppliers.

Dr. Rapp: Could we go on to the demonstration project? Because we've got 22 minutes for this. Why don't we get that out of the way and then ask some more questions and then allow the time for the recommendations.

Mr. Hartstein: I also want to add I understand that in some of your presentations, the payments amounts on the slide I just presented probably didn't show up because it was white on a white background. I certainly have a hard copy here that we can make a copy of to make sure everybody has the table I just presented. I apologize for that. I changed it to a white print for the purposes of the overhead because I thought that showed up better.

The one-year demonstration project. This is a one-year demonstration project to improve patient quality, to get certain information on standards of quality of care for physicians of care for physicians who treat patients with cancer. We wanted to maximize the opportunity to get information on these measures of quality from physicians, but minimize the burden that physicians would have to provide that information. To participate in this one-year demonstration project, the physician must treat a patient who has a diagnosis of cancer; they must provide chemotherapy through a chemotherapy IV push, or through infusion, and then they have to report the assessment of the patient's pain, nausea, and fatigue on a scale of one to four. To report, we've established specific G-Codes. There are four G-Codes for each measure, for each assessment that the physician has to report. So for instance, for the patient's scale of pain, there are four different G-Codes the physician would have to report one of those G-Codes to report the patient's assessment. The assessment of the patient's pain, there would be an additional four G-Codes to report the physician's assessment of the patient's nausea and vomiting, and then an

addition four codes to report the assessment of the patient's fatigue. And then as the last point says, the physician would receive a payment of $130 for doing these assessments and providing the information to Medicare. Just to reiterate then, several things would have to be on the claim; the patient would have to have a diagnosis of cancer, one of the codes for chemotherapy push or infusion would have to be on the claim; and then at least 3 of the G-Codes, one in each group to report the physician's assessment of one of these factors. I guess I just explain the slide again. It would have to do all of these things. The payment is not available to the physician if they don't report an assessment of all three of these indicators. If they only report one or two, then the payment is not available.

One other point about the demonstration project. Physicians will provide multiple drug administration services in a single day, but we are only going to make the payment of $130 once per patient per day, and then just a couple of key websites I want to bring your attention to because these are places you can get a lot of good information about the Physician Fee Schedule. The November 15th Final Rule is available through the Office of the *Federal Register* at this website, and then there is a whole host of data at www.CMS.HHS.govphysician/physicianfeeschedules/ASP. Actually, at this latter website, you can get the ASP information. So you can get the payments for all of the second quarter reported drugs; what Medicare's ASP plus 6 price would be for all of those drugs. And then I just also encourage physicians, if you go to the www.cms.hhs.gov website, in the blue area at the top, there's a drop down menu. If you click on physicians, it takes you to the physician information resource page. There is just a lot of great information there. The people who design our website have really put a whole abundance of information there that's of use to physicians. You can look up payment amounts in any area of the country through a menu driven tool, as well as information on the Physician Fee Schedule Rule. All of the information that's used to calculate the practice expense RVUs, information on enrollment and so forth. And so there's just a lot of

great information at that one website. And we've gotten a lot of positive feedback from the physician community on it.

Dr. Rapp: Great, thank you. Just a couple quick questions of my own on the one-year demonstration project. Did I see an estimate, or I thought I saw an estimate of the overall cost of this demonstration for the year?

Dr. Thompson: That's approximately $300 million.

Dr. Rapp: $300 million. And we've talked about a variety of demonstration projects and so forth and how they come about and what offices—what office is this out of and how did this come about?

Dr. Thompson: Kind of a joint effort between a number of CMS components, but again, ORDI, the area that normally would do our demonstrations, is kind of the primary focus of this within the agency, but had a great deal of support from the Office of Clinical Standards and Quality as well as from the Centers for Medicare Management. A team effort.

Dr. Rapp: What's going to happen with this information?

Dr. Thompson: The information in terms of the evaluation of the demonstration, again, ORDI will have the lead on that, as they do for other demonstrations, but again, with support from the Office of Clinical Standards and Quality, as well as Center for Medicare Management.

Dr. Rapp: OK, we have about 6 more minutes for questions and then I'd like to have recommendations and we'll start with Dr. Azocar, Dr. Castellanos, and Dr. McAneny.

Dr. Azocar: This demonstration, it is like a pilot project?

Dr. Thompson: That's correct. It's a one-year demonstration trying to assess the impact of doing standardized measurements, standardized assessments in these areas for patients with oncology. But it's a one-year demonstration project.

Dr. Azocar: Are you considering that there are other patients that they don't have diagnosis of cancer, they receive treatments that are chemotherapy. That is the case, like hepatitis C virus infection? Is just as significant, and they receive [?] like Interferon [?] and eventually as

the tendency to bring new drugs will be kind of similar to chemotherapy and you may see there are other situations for the future for. . .

Dr. Thompson: We've received those comments. People have identified other areas, and obviously our goal is to provide high quality care to our beneficiaries for this purpose of this demonstration, we're focusing on chemotherapy, but again we're getting comments and we'll need to evaluate how this demonstration works and then explore, have a continuing dialog going forward.

Dr. Castellanos: I got a lot of problems with this one-year demonstration project. As you know, the AMA together with CMS and the physician community, through the CPT Editorial Committee, RUC and the Practice Expense Advisory Council have pretty much controlled and done a good job with prices and reimbursement. As you know, based on the CMS Open Forum last week, the patients are expected to pay 20% of this demonstration project. And to date, there's no codes for the patient to submit to a secondary insurance. I have a significant problem, where you're having a Welcome to Medicare physical exam, which is a level 3, which gets paid and reimbursed about $97. That's a lot of work. And here you're doing a one-year demonstration project and that physician group is getting paid per day per patient $130. I would like to know how you came about that reimbursement figure.

Dr. Thompson: It is the case when the look at obviously the historically under the Physician Fee Schedule as you mentioned, the level 3, that was done, looking at kind of what's on the fee schedule now, looking at the relatively across there. When you start to move outside the bounds of the Physician Fee Schedule, which is what the situation you have here, this is not within the construct of the Physician Fee Schedule, this is a demonstration project. In looking at that and in what we felt, not there aren't other areas where we could have quality improvement as well, but in kind of examining the issue in oncology and cancer care, it did appear to us that it was an area as ripe as others, maybe even more ripe for activities in the quality area. There's been a lot of discussion in terms of reimbursement and payment for oncology services and our Office

of Clinical Standards & Quality was beginning and had some discussions with ASCO and others and patient groups with how to, not just talk about the reimbursement, but also talk about how do we improve the quality of care for cancer. And one of the areas that was brought up repeatedly by the patient groups was pain and nausea, and fatigue. And so we decided, OK, let's look at that. Fatigue, pain, nausea and vomiting, and what is it we can do there to try to improve the quality of cancer care and be responsive to what these patients were looking at. And again, not looking at this kind of well, let's try to crosswalk this to something on the Physician Fee Schedule, but looking at it as independently in the context of the demonstration. What was the value of this information, if we could through the use and looking at this and perhaps, one of the thought processes was reductions in ER visits and in-patient admissions for people that are having some symptoms of this. What could be a payment amount? And again, outside the Physician Fee Schedule, that would be appropriate for reporting of these, improving the standard of care, when we do the evaluation, what are the hospitalizations, what are the ERs, and looking at that unbalance, the number was 130. But not looking at that and understanding your point about the preventive physical. But again, this was kind of done outside of the Physician Fee Schedule and when you're looking at this well, how does this fit into the relativity of the Physician Fee Schedule, this is occurring external to the Physician Fee Schedule.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: Do you have recommendations on how this data is collected? Can it be on chemotherapy, oncology certified nurses, does it have to be nurse practitioners, PAs, MDs, can it be a form we write out, does it have to be a face to face encounter? Have you got any specific things about that? And my other curiosity was budget neutrality. This is not in the budget neutrality part. Is that correct?

Dr. Thompson: That's correct. We did not budget neutralize the $300 million for the demonstration, but again, that's something that's occurring outside the Physician Fee Schedule. And then in terms of the instructions, I'm not sure how close we are, but I know we're developing

some billing instructions—I'm seeing noddings so that's a good thing, with respect to those exact questions, and that's because we've seen those. We've gotten a lot of questions obviously you might have heard on the Open Door Forum as well as comments we've received after the publication of the rule, are going to some of those issues. We're trying to package all those up and have kind of a billing and educational document that's going to go out in the near future.

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: Mark, you have raised my antennas with that statement of this demonstration. $300 million more than if a trophy buck was walking across and I was sitting on my deer stand. We administer various medications in the office. Like Acutan or Retinoid. The patient comes in, matter of fact, our list adds ten more parameters, and it's inclusive in our office visit. And you going to—somebody's going to spend, tax payer's going to spend $300 million to examine the nausea, vomiting, or headache, which it is expectation, to see whether or not, you're going to pay them $130 in addition to what other fees they're being paid? I may be wrong, Methatrechsate, I'll go down the list, that's our office visit. If you're nausea, vomiting, diarrhea, I mean my antennas are so high that if I duck flies by now they tip the tops off of them.

Mr. Hartstein: I just want to add that we didn't use any of those methodologies to price this.

Dr. Rapp: We have 9 minutes left on this portion, so I would like to now recognize Dr. Castellanos for his recommendations.

Dr. Castellanos: I have several recommendations. The first recommendation is referring to the malpractice. PPAC recommends that CMS specifically identifies all data sources for determining the update for the professional liability RVUs. [off mike] The ones that you use.

Dr. Rapp: OK, can you read that back, Dana? Is there a second to that?

[seconds]

Ms. Trevas: PPAC recommends that CMS specifically identify all the data sources for determining the update for professional liability RVUs.

Dr. Rapp: That it uses for—is that what it is?

Mr. Trevas: All the data sources it uses.

Dr. Rapp: Is there discussion? If not, all in favor?

[Ays]

Dr. Rapp: All opposed. That's agreed to. Next.

Dr. Castellanos: Specifically related to least costly alternative policies. As Medicare implements the new drug payment system based on ASP, PPAC recommends that CMS consider whether these changes to Medicare drug payment system obligates the need for least cost alternative policies. At the very least, CMS should investigate carriers for application of the least costly alternative policies, and the increased burden it places on urology practices, which are already faced with huge revenue loss through patient care decisions in 2005 due to drug payment changes.

Dr. Rapp: I don't know if you could boil that down any better for us. Can you just state that, what's the issue?

Dr. Castellanos: The issue is that least cost alternative doesn't fit in with the what Congress has said was to determine the average sales price, but we heard CMS tell us this morning, based on answers that we asked them concerning questions we had at the last PPAC meeting, we are letting LCA, which is least cost alternative, create an unlevel playing field.

Dr. Rapp: What I'd ask you to do is just kind of work on the recommendation so it's a little more concise because I think we'll spend some time just trying to edit it right now. If you could just do that and then I'll entertain it.

Dr. Castellanos: OK, let me work on it a few minutes.

Dr. Rapp: Just try to make it a little bit more concise and boiled down so we won't have to try to edit it.

Dr. Gustafson: I think you're actually pointing at two slightly different issues, and maybe if it were two recommendations that would at least help the exposition of it.

Dr. Grimm: I'd like to propose that: PPAC recommends that CMS format the PPAC recommendation similar to the PRIT format, in that the CMS responses be available to PPAC members prior to the next PPAC meeting.

Dr. Rapp: Is there a second to that?

[seconds]

Ms. Trevas: PPAC recommends that CMS format the PPAC recommendations and responses similar to the PRIT format and that the responses be available to PPAC members prior to the next PPAC meeting.

Dr. Rapp: Is there discussion? All in favor?

[Ays]

Dr. Rapp: Opposed? That motion carries. Dr. McAneny?

Dr. McAneny: PPAC recommends that CMS institute a process to receive information from physicians of all specialties if they are unable to purchase drugs at the ASP price and have a process for instituting changes in ASP before the end of the quarter or make the changes retrospective to the beginning of that quarter.

Dr. Rapp: Is there a second to that?

[second]

Dr. Rapp: Do you have it written down? Read it again.

Dr. McAneny: PPAC recommends that CMS institute a process to receive information from physicians of all specialties if they are unable to purchase drugs at the ASP price and have a process for instituting changes in ASP before the end of the quarter and make that change retrospective to the beginning of that quarter.

Dr. Rapp: Is there a second to that? I heard a second. Is there discussion? So the basic idea of the motion is that CMS should institute some process that if Dr. Bergeron is having trouble getting the medicine he was talking about at the price or Dr. Castellanos is really talking

about that, that he would bring it to CMS's attention. And then CMS does what? They change the price?

Dr. McAneny: Well, currently, the problem is that they're asking—ASP is sort of unproven technology. Nobody knows what that's going to do. And it may really adversely impact the access to care in a lot of specialties—ASCO is geared up to provide us information, but I doubt that all the other specialties have been looking at that, so it's sort of unfair in November of 2004 to tell the specialty societies that they all have to be geared up to do this by January of 2005. And it may have leave us a physician purchasing a drug with no recourse if they discover that what they can purchase the drug for in Louisiana is under ASP and they don't get—there's no mechanism through CMS to say ASP was calculated incorrectly for this drug and people can't purchase it for that.

Dr. Rapp: But they would have to then retroactively change the price, either up or down.

Dr. McAneny: So if they fix ASP, then it would go back to January 1, and the drugs that you purchased and submitted on January 1st would then be fixed when they changed the ASP. You wouldn't have to eat it for that quarter.

Dr. Rapp: But conceivably the price could go down. You already purchased the drug. You thought you knew what they were going to pay for it, but now it's going to be different.

Dr. Castellanos: In that same line, we requested perhaps that CMS provide us with—you're setting the price for ASP, based on the data that you received from the companies that you received, yet you ask our specialty organizations to provide us with the names of those companies. Since you already have that data, why not provide to the physician community? Because it's a burden on our specialty organizations to try to gather that data that you already have?

Dr. Thompson: Just a point of clarification. It's not the same—we have data from the manufacturers, not from the distributors. So the list of people that are giving us the information

are the manufacturers. The manufacturers sell to the distributors. The distributors sell to you. So we actually don't know the middlemen.

Dr. Rapp: Can you read the recommendation back?

Dr. Urata: So, the plus 6, as your assumption is what the distributors are going to mark up the average sales price?

Dr. Thompson: The plus 6 is what the statute says we set the price, based on ASP plus 6 percent.

Dr. Urata: OK, but the distributors can mark up the sales price from the manufacturers by 10 if they so desire, or by 25, or by 25%, is that correct?

Dr. Thompson: The statute does not limit the ability of a distributor to set their drug prices.

Dr. Urata: OK, so forget about the statute. What happens if—

Dr. Thompson: That's the part where we trip a lot.

Dr. Urata: So you get the average sales price from the manufacturer and then you add six per the regulation, but then we purchase it from the distributor, and it's conceivable, or it's probably reality that the distributor increases it by 25. So we have a disconnect. Is that correct?

Dr. Thompson: To the extent that a distributor wanted to price themselves out of the market. If in fact, they decided to mark it up by 25% if the CMS was paying a price of ASP plus 6%, there's nothing in the law to prevent a distributor from saying I'm going to mark this up by 25%.

Dr. Urata: So the average sales price is the average sales price for manufacturers? Or should it be the average sales price from the distributors?

Dr. Thompson: The law says that it's the average sales price that the manufacturer is selling it for?

Dr. Urata: And yet we have to purchase it from the distributors at some kind of mark up. And that's where we get disconnected.

Dr. Rapp: You're talking about the average sales price they're selling it to the distributor, or the price that they're—

Dr. Thompson: I guess I'm saying the way the law is written, is that the manufacturers are telling us what they sell it for. More often than not, some manufacturers have direct distribution, manufacturers are actually selling that to distributors. And then the physicians are buying that from the distributors and what I'm saying is that the law says we take the price from the manufacturer, and add 6%.

Dr. Gustafson: That is for all classes of trade.

Dr. Thompson: That's correct. That's across all classes of trade.

Dr. Gustafson: So it includes sales by the manufacturer to hospitals and HMOs, not just individual physician offices.

Dr. Thompson: That's correct. The law does not say that the manufacturers are supposed to report to us only sales that ultimately end up in the physician class of trade.

Dr. Gustafson: The implication of that just to draw it out, is those are very large volume purchasers, who may be getting it at less than physician offices, that has the, will affect the overall price, as a result.

Dr. Urata: So are we sort of driving the patients to the hospitals to get this kind of treatment? In a sense?

Dr. Thompson: In terms of access, that's one of the things that we're going to be examining. Obviously, it's difficult to project what will happen on January 1, but we intend to actively, we have a structure in place that will be monitoring access through our 800 phone number, scanning activities, looking at the claims data, the carriers who actually obviously even get the claims data faster than we do, are also going to be looking at this. So that's one of the questions we hope that we've gotten the drug administration right and the drug payment right and so that we don't see sight of service shifts driven by other than clinical need. But we're going to be looking at that in terms of access issues.

Dr. Castellanos: Aren't we getting back, you're saying the supply who makes that sells it to the distributor, to me that's average wholesale price. And then the distributor is selling it to us at the average sale price. So aren't we getting back to the system that you just want to get away from?

Dr. Thompson: Again, we can get kind of far afield here, but the essentially the difference here is that when the manufacturer sets the average wholesale price, that really had no bearing on reality. Study after study showed that the price at which, the manufacturer would just say my price is $200. They could be selling the drug for $100. Their actual wholesale could be $100. So I think the difference here is when you have market data on their actual sales that they're giving us, versus a price that they're just telling us—

Dr. Castellanos: But it's still a wholesale price.

Dr. Thompson: The price is the average sales price that's correct. Depending on whether you look at it's wholesalers and other drug distributors, supply companies. But you are correct that it's essentially a price if you want to consider wholesale broadly, and think about it broadly, you are correct. It's the price from the manufacturer to the entities who are doing the distribution.

Dr. Rapp: It's fairly obvious that this is very complex and fascinating area that we could discuss all day, but why don't we have Dana read back the pending motion, and then we will discuss that motion and vote on it.

Ms. Trevas: PPAC recommends that CMS institute a process to receive information from physicians from all specialties if they are unable to purchase drugs at ASP prices as well as a process to institute changes in the ASP before the end of the quarter and make those changes retrospective to the beginning of the quarter.

Dr. Rapp: All right, that's been seconded. Is there any further discussion on that motion? OK, all in favor of the motion, say Ay.

[Ays]

Dr. Grimm: Do you want to stay "retroactive," not "retrospective?"

Dr. Rapp: OK, that's without objection. All in favor?

[Ays]

Dr. Rapp: All opposed? OK, that motion carries. So we've run out of time for this particular session, so if you got your other motions, we'll get to those in a bit, but I want to move on to the next topic and I want to acknowledge Mr. Hartstein's noting that he's definitely presented here many times before, and he's always done so in a very highly professional way and I think he's a credit to our government, so thank you for your presentations in the past. I am expecting that some day you'll be back to thank you. [applause] OK, I'm sorry to cut this off, but as I say, I think we could go on indefinitely on this subject and then we would be hopelessly behind, but I'll give you an opportunity, Dr. Castellanos, to do your additional recommendations and to the extent that any members of the Council that have additional recommendations if you could distill those recommendations down and write them out on paper, it would probably save us a little time, because we could just give them to Dana. She won't have to go through the process of making sure she's got it right and then we could just do it a little bit faster.

OK, the next item on the Agenda is the 2005 Outpatient Prospective Payment Final Rule. We have four members of the staff from the Centers for Medicare and Medicaid Management that will be discussing this. Ms. Elizabeth Richter, who is the Director of the Hospital & Ambulatory Policy Group, over there on the right, Ms. Cindy Read, Director, as long as you're sitting behind your proper names there. You're not going to trick me like the Council Members, are you? Ms. Cindy Read, Director of Division of Outpatient Care, Ms. Joan Sanow, Deputy Director of the Division of Outpatient Care, and Dr. Carol Bazell, Medical Officer. So they're going to discuss a number of things here, and I think, Ms. Richter, are you the one that's going to start?

Ms. Richter: Sure. Just briefly, To say that we have a number of issues. We're going to actually start with two issues we'd like the Council to consider specifically. Dr. Bazell will start

with that and then we'll walk you through the highlights of the Final Rule. So, with that very brief introduction, I'll turn things over to Dr. Bazell.

Dr. Bazell: Good morning. Thank you for the opportunity to be here. This morning we're going to update you on Outpatient Prospective Payment System calendar year 2005, Final Rule. And as a reminder, the Outpatient Prospective Payment System is that system that's designed to reimburse hospitals for the resource costs associated with providing services to Medicare beneficiaries. This morning, we're going to give you just the highlights of in a variety of areas. Those will include the update in payment changes for 2005, the implementation of a variety of MMA provisions that affect this payment system, an update on payment for preventive services, which are provided in the hospital outpatient setting, a little bit of detail about our payment for clinic and emergency room visits, and observation in hospitals, perspective on the drug administration that occurs in hospitals outpatient settings, and then some other assorted payment issues we categorize as special payment issues.

Because of the experience you bring to this area, as you hear the presentation today, we have several things that we be interested particularly in your input on. We've had a lot of discussion on the hospital outpatient side about our payment for observation services in particular. That's observation associated with emergency room visits or patients admitted directly to observation from physicians' offices, or through the clinic. The patient status, whether a patient is in observation or inpatient status, affects significantly how hospitals are paid. We've been told that physician orders are required to admit patients, but sometimes there seems to be some confusion between hospitals and the admitting physicians about the particular status the physician has admitted or intended to admit the patient to—whether that be inpatient or observation. And that confusion can arise from either side or from both parties combined. So we're interested in your thoughts about how we can educate physicians about the importance of making a clear distinction—that means, making it clear to the hospitals in which they're taking care of their

patients—between an order to admit a patient to observation versus an order to admit a patient to inpatient status.

Do you want to take questions during here or would you like to circle back?

Dr. Rapp: If you're ready to do that?

Dr. Bazell: I just saw a hand over here, so…

Dr. Urata: You want an answer? Are we supposed to email you or something?

Dr. Bazell: No, we thought what we would do is provide the considerations for you up front and then we would circle back with the questions after you've heard a little bit more about some of the issues in here. We thought it might be helpful to have some of the specific questions to begin with as you hear the rest of the presentation. Is that all right?

The second area in which we have actively solicited some input in our final rule, and we would be interested in your input as well is the specific way in which the hospital Outpatient Prospective Payment System pays for new technologies. In particular, there is a provision that requires the Hospital Outpatient System to make separate payment for new devices that meet our pass-through criteria. These are new devices and there are a variety of criteria that are involved here. Essentially new devices, that because of their newness, they are not reflected in historical hospital claims data that are used to set the payment rates for them. And so we make a commitment for devices that fall into this category to pay for them for a couple years at charges reduced to cost to allow adoption of them and remove any barriers that might be cost barriers to adoption of the technology. Currently we have a requirement that devices must be surgically inserted, entered into the body through a surgically created incision. And we've been asked by a number of commenters to allow pass-through payment for devices that are introduced into the body through a natural orifice.

So we're soliciting comments and would be interested in your thoughts that address the following questions. And there are four of them outlined here for you. The first is whether a distinction should be made between natural orifices and surgically created orifices at all. We're

aware of many new advances in technology and perhaps that distinction is an artificial one that we no longer need to make.

The second question is how might a new device that surgically inserted through an existing orifice be distinguished from older technology, which is also inserted through an orifice. Essentially, this gets to the definition of new, and whether there are any specific considerations we need to keep in mind if we were to consider technology that is utilized through natural orifices.

Third, what distinguishes a device inserted through an existing orifice from surgical supplies, sutures, clips, surgical kits, etc., because we've made a distinction in the past between those items.

And lastly, what distinguishes instruments that are supplies when used for open procedures from those passed by a scope through an orifice, particularly with respect to endoscopic techniques. We're concerned about our ability to define a device in that setting.

The key website regarding the Hospital Outpatient Prospective Payment System is the site listed here. On that site, you will find the Proposed Rule for 2005. The Final Rule for 2005, as well as a variety of supporting data files that address payment for specific services which might be of interest to you or to the hospitals that you work with.

Turn it over to Ms. Read for the next part.

Ms. Read: OK, thanks, I'm just going to start to give the overview of the changes that we announced in our *Federal Register* notice of November 15th, and I'd say also that the comments are due on that January 3rd, and I'm soliciting comments in addition to the pass-through device issues that Dr. Bazell just mentioned on the placement of new codes within the ambulatory payment classifications or APC. So for the 2005 update, we recalibrated all of the relative weights for the clinical APCs out of about 800 APCs, approximately 500 of those are for clinical services, procedural visits and so forth. And we updated the relative weights, using the most recent claims data. That was in 2003 Hospital Claims Data and latest cost reports from the

hospitals that billed for services under the Outpatient Prospective Payment System in 2003. The Payment Update includes a 3.3% market basket increase to the payment rates. We've projected that the 2005 payments will be approximately 24.6 billion compared to the 23.1 billion for Outpatient Prospective Payment System services that was predicted for 2004. Overall, the percentage payment increase for these services is for 4.0%. That's higher than the 3.3% market basket increase because we projected that for 2005 our payments for pass-through devices and drugs would be somewhat less than we projected in 2004. We are allowed to spend 2% of the total payments on these pass-through items and the amount that we don't project that we'll be paying for those items is put back into the conversion factor and spread across all services. So the payment overall payment increase then went up from 3.3% to 4.0%. The mid-volume urban enroll hospitals will do the best under the payments changes, with 5% or higher overall increases. A large urbans will see about a 3.9% estimated increase and rurals, 4.5% increase.

The Final Rule for 2005 included discussion of implementation of certain MMA provisions. We've revised our payments for drugs and biologicals in accordance with the MMA provisions for 2005, specifically for those drugs and biologicals that are defined by the MMA as specified covered outpatient drugs, and those include all radio pharmaceuticals and drugs and biologicals that had pass-through status as of December 31, 2002. For those items, the MMA specifies that the single-source drugs be paid at between 83 and 95% of average wholesale price, or AWP. The multi-source innovator drugs are capped once again at 68% of AWP, and the generic drugs are capped at 46% of AWP. For 2005, at the moment, we have 23 drugs for which we have established pass-through status and for which pass-through status does not expire in 2005. The MMA requires that we pay for pass-through drugs on the same basis as drugs provided in physician office settings, so that's ASP based payment methodology. We allow separate payment for drugs for which the per day cost is more than $50. That again was specified by the MMA for 2004 through 2006. When we do our recalibration, we look at the average cost per day for drugs. If it's less than $50, then we package the cost of those items into the services with

which they are associated, typically the administration codes. The MMA also required that for 2004 through 2006 we pay for sources of brachytherapy at a rate that hospitals charges that are adjusted to cost by using a hospital overall cost-to-charge ratio. And for 2005, we will continue to hold harmless provision for small rural hospitals, that is those with 100 beds or fewer, and sole community hospitals located in rural areas. The MMA also included a provision for drugs for which there is not yet a HCPCS code assigned, and under those provisions and according to the way we have provided for the implementation of that provision in 2005, hospitals will be able to bill for new drugs as soon as they received approval, using an unspecified code, and be paid at 95% of AWP until we've assigned a code for that item.

The MMA also specified that payment for all mammograms provided in hospital outpatient departments would be paid outside of the OPPS and we therefore proposed and finalized a provision to pay for diagnostic mammograms under the Physician Fee Schedule. We had already moved payment for screening mammography to payment under the Physician Fee Schedule several years before. And this results in an increase of about 40% for those services. We're also going to be paying for the new Welcome to Medicare physical for when those physicals are provided in the hospital outpatient setting. We'll be implementing the codes for the examination and the EKG tracing. We've assigned those to the clinical APCs. The exam portion is in the middle of a clinic visit, and the EKG is in the EKG APC. And we'll be paying a total of about $78 for the hospital for the cost of the facilities and providing those services. Thank you.

Ms. Sanow will continue.

Ms. Sanow: Yes. Good morning and thank you. The payment regarding clinic and emergency room visits and observation services furnished in the hospital outpatient setting. For 2005, the payment rates for clinic and emergency room visits will increase by approximately 4% over their 2004 levels. For clinic visits, hospitals would receive a range of between $51 and nearly $80 for clinic visits, depending on whether it's a high, a low, mid-level or high visit, and for emergency department visits, the range in payment to the hospital would range in $77 for a

low-level emergency department visit to $234 for a high-level emergency department visit. We are continuing. I'm going to jump down to the 3rd bullet, and just address the fact that we are continuing to use the existing CPT-Codes in the hospital outpatient setting to bill for both clinical visits and emergency room visits. Hospitals have continued to be concerned about using these codes, which describe those visits more in terms of the professional services that are rendered, rather than the facility services furnished by the hospitals itself. But we are continuing to work on developing new codes for the Evaluation & Management services furnished by a hospital and we are looking at guidelines that have been prepared by some outside organizations. We are trying to review those test them, we have not announced any plans for implementation of those at this time. We will give hospitals ample opportunity to comment on new coding and guidelines at such time as we would issue them. And ample time to actually administer those once they would be announced and reviewed. Related to a fusion between clinic emergency room visits, the patient status and observation. Observation status is paid for under the Hospital Outpatient [?] S. There are three conditions for which we make a separate payment for observation services furnished in connection with congestive heart failure, chest pain, and asthma, and we've been doing this for several years. There are specific criteria that have to be met in order for a hospital to receive separate payment, and the status of the patient, it becomes quite important from the hospital's point of view, as to whether they are in observation status, or have been admitted as an inpatient. And that's one of the questions for consideration that we hope you can give us some feedback on as to ways that we might improve a better understanding. Hospitals are concerned about it and it's something we would be interested in your thoughts on. So we've tried to simplify these criteria that the hospitals have to meet in order to receive separate payment for observation and one of the things that we've done is eliminate requirements for specific, the performance of specific diagnostic tests, which previously we had made a requirement of. This proved to be very burdensome. In some cases, it may have resulted in unnecessary tests being furnished and we are assuming that just as part of standard care, some of these very basic tests, like EKGs and pulse

occimetry and so on would be furnished. So we are no longer making payment to the hospital contingent upon provision of those specified diagnostic tests, beginning in 2005.

Regarding drug administration: We are making quite a change on how hospitals will be reporting drug administration services beginning on January 1, 2005. We are moving from a series of Q-Codes that have been used since the inception of the Hospital Outpatient PPS, to a CPT-Code reporting system. We however, are not adopting the G-Codes that are going to be used under the Physician Fee Schedule. Rather, we are going to instruct hospitals to use the existing CPT-Codes for drug administration. We did that because we felt if in fact CPT were to revise those codes again in 2006 to have hospitals move from Q-Codes to G-Codes, then to new CPT-Codes could be problematic. Also, hospitals tell us that they use the current CPT-Codes predominantly for other payers and it would be a much less burdensome requirement for them to begin using those same CPT-Codes to report drug administration for hospital outpatients. We are paying for these through a crosswalk of those CPT-Codes to the existing Q-Codes for which we have data, but the data that we collect in 2005 charged data will be the basis for coming up with code-specific payments in 2007.

There are a couple of additional payment issues that we addressed that are of concern to hospitals. One has to do with payment for blood and blood products. We developed a new methodology for determining payment for blood and blood products. I won't go into the details of cost-to-charge ratio simulations and such. Suffice to say we've created an individual APC for each blood product that a hospital might furnish and leukocyte reduced red blood cells, which is the most frequently billed blood product from hospitals, the median cost, using this new methodology, increased by 32%, so payment for that particular product will go up considerably. We also to ensure that some low volume products, payment would to go down too much, we are phasing in some changes that we used to calculate payments for blood and blood products, we're going to phase it in using a blended payment methodology. Regarding payments for devices: Devices, of course, are another area of great concern to hospitals, to ensure that they receive

adequate payment for what can be very expensive items that they insert surgically; these are implanted devices. We have made some adjustments in trying to ease what apparently our data suggest are reductions in cost for device-related procedures. We've specifically identified a series of APC that we've determined are device-dependent. That is, the procedures that comprise those APCs, individual CPT-Codes could not be performed without insertion of some kind of device. And we are requiring hospitals for a subset of these device-dependent APCs where [?] hospitals to furnish us with a C-Code or J-Code, I'm sorry, L-Code, whatever is appropriate, the HCPCS-Code that describes the inserted device so that we can collect data on the cost of individual devices; something that hospitals, our data suggest, have not been doing in a consistent way. The final thing that is a rather significant change in the 2005 Outpatient PPS is the outlier payment. We are not only using a percentage relationship to define what constitutes an outlier—in other words, the cost of a service has to be greater than 1.75 times the payment amount in the APC for the service, but also the cost must be greater than $1,175. We found that there were a number of outlier payments going to hospitals for services that were really relatively low-cost. We believe that the addition of this fixed dollar amount threshold will ensure that outlier payments really are being targeted for complex procedures that cause the hospital to incur higher costs and that pose a more serious financial risk to the hospitals. Also, one thing that is not mentioned under special payment issues, because it's not special per se, in other words, it's a regular feature of the outpatient PPS, which is the inpatient list. I just wanted to point out that this year we have assigned 22 CPT-Codes that are currently on the inpatient list, we have assigned them to APCs for separate payment beginning in January, 2005, and the final slide is numbers and email addresses and if you wanted to contact us, we would be more than happy to answer your question in more detail or address any questions you might have currently.

Ms. Richter: If I could just point out my email address actually is LRichter@cms.hhs.gov, so if anybody wants to contact me, it will go into cyber space if you use the one on this slide.

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: Yes, ma'am, Ms. Sanow, I practice in Shreveport, Louisiana and the electricity to the hospital and to my office, the natural gas, the water, payment of property taxes are comparable. I'm hearing here increases which are beyond my comprehension; 40% for this reimbursement, 4% here, 2% here. Could I possibly have your secret methodology scheme and put that into my scheme as Physician Fees. What's the just—40%? 4%? Fees are being, and yet we have the same expense. I really would like to get that and extrapolate that and put it into some of our physician fees, if you're talking about the cost of doing business, etc.

Ms. Sanow: Well, the quick answer to this is that first of all these are two, under the statute, are two totally different payment systems. We follow Section 1833T of the Social Security Act. And further, I would like to point out that where payment for a service under the OPPS increases, there are concurrent decreases in other services, because the hospital outpatient PPS is budget neutral, and we have to ensure that it's at relative weight system similar in some ways to the physician fee schedule. So for the areas where services increase, that reflects the hospital's cost relative to other services that they furnish during the course of the year.

Dr. Castellanos: Can I respond to some of the questions you asked?

Dr. Rapp: That's what I was about to get to. So let's just sort of go back and through those in an organized way. The first one that you presented to us was how can we educate physicians about the importance about making a clear distinction between an order to admit to observation and an order to admit to inpatient status. So I think Dr. Urata and Dr. Castellanos are about to answer that question. But let me ask one of you first, because I think it was mentioned that this status differential is of great importance to the hospital. Could you elaborate on that a bit?

Ms. Sanow: Yes, if a patient is placed in observation status, all of the services that are furnished to that patient are paid for under the hospitals Outpatient PPS. The hospital uses a distinctive bill type to report all of those services to Medicare for payment, whereas if that patient

is admitted as an inpatient, the payment system is under the DRG inpatient PPS, all services would be bundled up into the DRG. It would be an entirely different bill type that would be reported to Medicare. The services would be paid differently. And in some cases, once a patient status is determined, it is problematic about changing that in midstream. It causes all kinds of claims processing issues and program integrity issues and so forth.

Dr. Rapp: In other words, if you admit the patient as a regular inpatient, and then try to go back to observation that would be a problem, and is the reason for that because there's the issue of denials, unnecessary admissions? They get denied and they don't get anything, right?

Ms. Sanow: In some cases, hospitals could be denied payment for services that are actually rendered.

Dr. Rapp: But if they come in for observation, that would tend not to be a problem.

Ms. Sanow: If in fact the patient belongs in observation, and is appropriately placed in observation, so as to determine whether they need further care as an inpatient, or whether the problem can be resolved and they can be discharged or released from the hospital, then any diagnostic services that are furnished would be paid under the outpatient PPS.

Dr. Rapp: Now, on the other hand, if the physician admits the patient to the hospital, there are certain codes that they use that may be, if they, like an initial assessment, and those of you who do inpatient hospital work, you have special codes for the inpatient evaluation, right? Are there different codes if they are under observation? So, and the money to the doctor for the inpatient would be significantly different, probably. Little bit different. Dr. Castellanos?

Dr. Castellanos: I think basically he's hitting the nail right on the head. I think we are all on the same team. We really want to work with you and obviously you want to work with us. I think you need to let us know which is the best benefit for the patient and the system. Which costs more? Now, if I know that if I put somebody in observation and may need to transfer them to admit, I would do that. If I've put it in the admit and it's much more expensive, then obviously, I

would like to try to help out the system. So you need to let us know a little bit about the finances, and which is the benefit to CMS and to the system. Do you follow my answer, or request?

Ms. Richter: I think that one of our concerns here is actually the definition of whether someone should be in inpatient or outpatient is actually a medical necessity issue. So it's not, well, everybody, I think the concern for the trust fund is an important one. The real issue is what is the level of care that the patient needs. And if the patient needs to be observed for a while and then ultimately admitted, that's fine. That happens frequently. That's what observation is for. But if the level of care they need doesn't rise to the level of an inpatient admission, they shouldn't be admitted, they should be treated in the outpatient sector. And so it's a medical necessity issue, rather than a payment system issue. It has payment system implications. But the fundamental issue is a medical necessity one.

Dr. Rapp: But when they end up for observation, they could be in exactly the same place in the hospital, right?

Dr. Castellanos: Same beds, same everything.

Dr. Rapp: As an emergency physician, what I was impressed with, have been impressed with over a number of years, is that the length of hospitalization can be abbreviated more than it ever has before. A person could be admitted for chest pain and they may only be there for 48 hours, which typically would be something you might consider, I mean frequently only 24, but maybe 48, and you would frequently think that that would be maybe something that observation would be appropriate for, as opposed to a more lengthy time, so maybe the OBS is part of the question about whether they're observation, not whether they need to be admitted for a more prolonged stay is just how long do you expect them to be there? Would that be a legitimate consideration? You may not expect them to necessarily be there more than 24 to 48 hours just because of how hospitals work these days. I would say in terms of educating us about the importance of making a clear distinction, that's probably, we need to know more details about the significance of those things in what you consider appropriate. But I think if it's just, do they need

further hospitalization, do they really need hospitalization? That's a philosophical question I suppose. Dr. Hamilton was next and then Dr. O'Shea.

Dr. Hamilton: I just want to clarify in my mind what you've said. Apparently it's easier to move from observation status to inpatient status whereas if you admit somebody as an inpatient and decide well, they really should have been on observation, then that is really much more difficult, is that basically correct?

Ms. Sanow: We know from hospitals that this is problematic because getting back to what Liz has said, it's a medical necessity issue. And if a patient is admitted as an inpatient—if their status is inpatient, and it's subsequently determined that their need for care didn't really rise to the level of inpatient services, that if they would have been more—they didn't meet the criteria of that hospital for an inpatient admission—

Dr. Hamilton: Well, I think this is probably simpler than it seems. I mean to use your example, if a person comes into the emergency room with chest pain, or into your office and you send them to the hospital to rule out myocardial infarction, as it were, and it turns out that they don't have it and you can determine that in 6 hours or so, then obviously observation is what they needed to be. So whenever you're considering this, if you admit them to observation, do the appropriate test, and usually within 6 to 8 hours, you can make that determination if they then in fact do need to be in the hospital, you then can transfer them to a regular admission. That's not—if that's correct, it seems rather simple to me.

Dr. Brazell: I think that's one type of situation that might be relatively straightforward. We've heard from hospitals about lots of other kinds of situations where it may be less clear or they may be more on the borderline. They admitted them because they really thought that's what they needed to do, and then they only really needed 18 hours to do what they needed to do and then the patient could go home, and then somebody says, well, maybe that patient really didn't rise to the level of –

Dr. Hamilton: So why not in most situations where it's not clear, why not admit them to observation, and then move them to inpatient status if it's appropriate, if that's the simple way to do it?

Dr. Brazell: I think that would be one approach. As Ms. Sanow said, the issues on observation, in terms of payment for observation, on the outpatient side, she mentioned three conditions for which a separate payment is made for observation in the outpatient in asthma, congestive heart failure and chest pain. In the rest of the cases, for observation for other conditions, that observation payment is bundled into the payment for the visit, for instance, the emergency room visit.

Dr. Rapp: But is it an hourly rate, or something like that?

Dr. Brazell: No, it is a one-time payment for observation. And you have to—

Dr. Rapp: What if they're there for 2 days?

Dr. Brazell: You have to be in observation at least 8 hours to be eligible for the payment. There's one payment, even if they were there for 2 days. And we've said, we don't think observation generally would extend beyond 24 hours in most cases that we can think of from a medical perspective.

Dr. Rapp: OK, Dr. O'Shea, Dr. Urata, Dr. Powers, and Dr. McAneny.

Dr. O'Shea: I agree with the observation. From my standpoint, it's a medical acuity. I think you have 2 separate things going on here. You have admissions directly from an outpatient office, versus admissions from an ER. I think we're sometimes being driven towards making decision on both levels; acuity of the patient, as far as their own status, and that may also definitely play into it, a 40-year-old being admitted for chest pain is different than a 78-year-old being admitted for chest pain. The example of chest pain I think maybe can make your own criteria. That is an 18-hour protocol actually, 3 components before discharge, but I think that that may be the status of the patient can maybe be one of the ways that we can document best, if we really want to give a criteria, a number. So acuity of the patient should actually, I think play into

that—who would be most likely maybe not to do well after the first 23 hours and need a longer stay.

Dr. Urata: In our hospital, we seem to be educated to do mostly observation and then transition over to inpatient if acuity warrants it. But rarely, we have a patient who gets better, despite high acuity after the fact that we've admitted him for inpatient. And I guess from my discussions with the hospital when I saw this issue on the agenda is that they're always concerned when going from inpatient to observation and does Medicare consider that fraudulent or something of that nature? When in fact, the patient might initially have had high acuity, but subsequently got well quick and was discharged. So but of course there's also the mistake of physicians admitting to inpatient, not realizing what all the rules are. Those folks are being educated by the hospital because it affects the hospitals. So I was thinking maybe there could be some window of opportunity to switch from inpatient to observation if it was clear that that the level of acuity wasn't going to go up to meet the criteria for inpatient.

Ms. Sanow: Well, as it happen, the National Uniform Billing Committee has established a code, condition code 44, which is a new condition code. We issued instructions to hospitals several months ago about use of this code. In the circumstances where a patient is admitted and it is subsequently determined that while the patient is still in the hospital and with the concurrence of the ordering physician, that that admission as inpatient really was or should have been or was more appropriate as an outpatient admission, then hospitals can report the episode of care as an outpatient episode of care, using that condition code and they would bill for it as an outpatient episode of care. We are in the process, we've received a number of requests for clarification from hospitals about the circumstances surrounding use and we're working on those now. We may be issuing some subsequent guidance and clarification of this.

Dr. Urata: It's clear in our hospital there are a few doqs who can't figure it out, I hate to say. And it's very frustrating to some of the utilization nurses. It just drives them nuts.

Ms. Sanow: And I want to emphasize because this question came up just this past week from our San Francisco regional office, a patient's status goes with the patient, not with the place where that patient is deposited. So a patient could in fact be in a bed for observation, and then their status is changed of inpatient, and they could remain in the same bed. So to say that in order to be a patient in observation, you have to be in an observation bed, or you have to be in an observation unit or an observation suite, is from Medicare's perspective at least, is not the critical factor, it's the status of the patient on the record that is the key.

Dr. Rapp: Dr. Powers?

Dr. Powers: It seems to me that rules change on occasion and it's hard for the physicians to keep up with, you know. Can we have one-day observations or two-day observations and over the years things have changed to some extent. But to some extent, it's the hospital's responsibility to keep on top of that, too, instead of just us. But they've educated us. If you have a good hospital, they let you know and if I make a mistake and enter someone in under regular admit, before they get to the floor, someone usually calls me and says let me just give you some information, and I give the final order what I want. But I'm given information about that, so I think a lot of hospitals are already aware of that 44 and the appropriateness. But I think a lot of DOQs know, too. I mean we know if it's a congestive heart failure that you admit into observation. And the unusual ones, where it just so happens that you admit in acute care, there's no way of knowing ahead of time that that's going to happen. And so my guess is that if this is going on a lot, if the hospitals are asking to educate the doctors that maybe they're not doing a very good job.

Dr. McAneny: It seems to me that the whole existence of observation status is another example of no good deed goes unpunished. For example, when a physician tries to do something very efficiently, and get somebody out quickly, what happens then instead of being in the inpatient part A pot, they're suddenly in the outpatient Part B pot and therefore contributing to the

volume and intensity of physician services and helping us to trigger that SGR cap that gets them lower rates. Is that not true?

Dr. Brazell: Outpatient services are not included in the SGR.

Dr. McAneny: Well, I was told hospital outpatient services, all of them, drug administration, if they move that to the hospital, if they move them to the hospital, I was told that all that triggers the cap. That's not the case?

Ms. Richter: Hospital outpatient services are not included in the SGR.

Dr. Phillips: Let's be clear about what—

Ms. Richter: The physician services provided in a hospital outpatient, like all other physicians services would be included, but the payments to the hospitals themselves are not included.

Dr. McAneny: Now the payments to the hospitals are not included—if the testing is done, is it outpatient or inpatient testing and does that contribute to the volume and intensity?

Ms. Richter: If it's paid under the clinical lab fee schedule, it would be included.

Dr. McAneny: And the X-rays, and the things to rule out pulmonary embolists and the EKGs to rule out MI and all the stuff that you do, all the testing that you do to get that patient out of the observation period, does that contribute to the volume and intensity or not?

Ms. Richter: If it's paid to the hospital as an outpatient PPS service, as opposed to a clinical lab service or something like that, it is not included.

Dr. McAneny: So X-rays are not?

Dr. Brazell: Services like X-rays and EKGs are paid in the hospital under OPPS. So those types of diagnostic studies not clinical lab studies would be paid under OPPS is not included.

Dr. McAneny: So the only thing that would contribute is the clinical lab that you get in the outpatient system. OK.

Dr. Rapp: I have a couple suggestions. If it's true that the observation is typically for 8 to 24 hours of hospitalization, is that right? Has to be more than 8 and typically less than 24.

Dr. Brazell: We have said that we will not make a separate payment for the conditions unless someone's in observation for longer than 8 hours. And that we would expect in general that it would not last longer than 24 hours.

Dr. Rapp: All right, so perhaps you could just encourage doctors when they write their orders to always write, Admit to inpatient status, or admit to observation status, as opposed to typically doctors just write admit. So—

Dr. Urata: On our order sheet, we have a box that we have to check now. Well there's two boxes, we have to check one or the other.

Dr. Rapp: Then to tell them to put some kind of information that typically observation is less than 24 hours, so really it's admit to the hospital for 8 to 24 hours or admit for more than 24 hours.

Dr. Urata: I thought it was 48 hours now for certain things for Medicare.

Dr. Brazell: We have not provided actually for 2005, won't be provided an upper bound for the observation.

Dr. Rapp: Well, you can keep them—I mean, assist is—

Dr. Brazell: In a given situation, it ended up lasting longer than 24 or 48 hours, that would be permissible pending medical review that might be done locally or whatever. But we make one payment however for those cases in which we pay separately.

Dr. Rapp: It just seems to me for the doctors, if you just make it not so complicated. Just say, if you anticipate the person's going to be in there less than 24 hours, admit to observation. If you anticipate they're gong to be there more than 24 hours, admit to inpatient and then make clear, that it doesn't matter where they are in the hospital. That the physical sight, because they also write, admit to 5 West. Make clear that it doesn't it still doesn't matter where they are in the hospital, even in the emergency department. They could be admitted to observation. I think those would make it clear. And then thirdly what difference would it make to anybody? Does it make

any difference to the government? Does it make any difference to the hospital? Does it make any difference to the doctors?

Ms. Sanow: It makes a big difference to hospitals.

Dr. Rapp: And what is that?

Ms. Richter: It depends. I mean the payments are different for services—it depends on what service it is, and what combination of services you're providing. Sometimes the inpatient payment or the DRG amount could be more, other times it could be less. It depends on what services you're providing, what they're particular payment rates are in the outpatient and what the DRG would be in the inpatient setting.

Dr. Rapp: So the status should not be retrospectively determined by how many services were provided. Maybe you should make that clear. It really should be a prospective assessment of how long you're going to be in the hospital.

Ms. Sanow: Exactly. And that is consistent with the Medicare definition for "admission." It's a formal admission by a physician or person who's legally authorized to admit a patient to a hospital with the expectation that they will occupy a bed over night and require inpatient level of services. Even if it turns out they don't occupy a bed overnight in that they are transferred to another facility or for some reason it is determined the problem resolves itself and they can be discharged.

Dr. Rapp: Well, I think the education of the doctors will be helped if you make clear in your own mind what you think are the criteria. Once you figure out what you think the criteria are, because doctors don't necessarily think this way. This is really generated by money, rather than, we think, well, let's put you in the hospital til we figure out what's wrong with you or make you well enough to go home. That's what we're thinking. And we're not really thinking about patient DRGs and this separate payment and this sort of thing. Hospitals make us think about that because they come down and talk to us about that. Dr. O'Shea, then Dr. Urata, then Dr. Powers.

Dr. O'Shea: I'm really going to reiterate this but yes just that I've had patients for less than 24 hours for myocardial infarction, drug detox, that kind of thing, and they go to the ICU. So it really is a temporizing measure, or should be seen as a clock measure, and if that's the way they're supposed to be, then that's the directive they could put forth.

Dr. Rapp: Dr. Urata:

Dr. Urata: In some ways, it sounds as though we should just take care of the patient and admit the patient and treat him the way we think we should treat him and let the hospital decide if the level of treatment was outpatient or inpatient depending on how much work the nurses had to do on this patient, based on my orders and my treatment. And you know, here I am, I'm writing all these orders and at the same time, I'm trying to figure out, see, is this intensity of service equivalent to an inpatient or an outpatient, and there's all these criteria, but I don't really think of it that way. I think of it as what does the patient need, and what kind of medications and does the patient need oxygen, you know, and thinks of that sort. And how many X-rays should I get or blood tests in the morning and try to get an estimation of when I think the patient could go home because that's one of the things that they want to know, when can I go home, doc? And it seems if the nurses, or if the admitting specialist could figure out well, gee, this meets Medicare's criteria for inpatient intensity then this should be an inpatient. But I've kind of figured it out to this point.

Dr. Rapp: Dr. Powers?

Dr. Powers: I think to a large extent that we as physicians don't understand the intensity of the services that the hospital provides as being different in one case than another. If I admitted a patient for a TIA and keep him there for 24 hours, I'd do pretty much the same tests I'd do in the first 24 hours of a patient with a stroke. Now in the subsequent days, there may be a difference in intensity of service because one goes home and one stays in the hospital and gets therapy and that sort of thing. But from our perspective, we don't necessarily see the difference in intensity of services the hospital provides and we kind of go by diagnosis and time. As far as I'm

concerned, they still get their vital signs every four hours, they still get an IV, they still get this, they still get that. From the nursing perspective, the hospital perspective, they still get all the tests done in the first 24 hours.

Dr. Brazell: When you do admit a patient to observation, in that kind of situation where you weren't really sure what was going on with the patient, you would have potentially some expectation in your mind that that patient might be able to leave in 24 hours if you sorted out whatever it was.

Dr. Powers: Right, it's more a time issue for us than it is an intensity issue. I mean we've always seen it as a time rather than an intensity issue.

Dr. Rapp: And that's the problem with the Outpatient Prospective Payment System. It doesn't allow for additional payments to sort of expedite the work of a TIA for example. If you're not going to pay for any of it, OK, we'll keep him there three days. It's sort of self-defeating. Dr. McAneny?

Dr. McAneny: I think I'm being intentionally dense on this issue because, maybe unintentionally, too, but the whole things seems sort of silly to me. It seems to me that you ought to make the payment equal for the service that's given and just eliminate the whole category of observation and if we do things nicely and efficiently, and the patient gets to go home early, that's good. But if you're doing the same thing when Dr. Powers admits a person with a TIA and doesn't know whether it's going to turn into a full-blown stroke or not, why put in all these artificial distinctions and say this one's observation, and that one's the other. If there's some consistent difference in the payment mechanism so that the hospital gets more money if you do it this way than if you do it that way, then I can see why the hospitals are pushing us to do that. But clinically, you don't know what's going to happen in the future unless you've got a really good crystal ball and so it's sort of silly, and those are hard to acquire, yes, then to try to guess whether or not the patients going to be able to go home in 18 hours when their MI is ruled out or whether they're going to stay and have their bypass and everything else done.

Dr. Rapp: Mr. Lanigan's going to provide us with crystal balls. Well, we're running out of time. She's got like four other questions here.

Dr. Brazell: They're just sort of subset questions of the general issues?

Dr. Grimm: Can we email you some answers to these? That might be a better way to do them, get some suggestions to everybody.

Dr. Brazell: I was going to say they fall in generally the category, if we were to think about expanding our definition of devices that we pay separately for that are new to devices that are inserted through natural orifices of the body as opposed to through a surgical incision, are there any things nuances that we should be really cognizant of regarding how we would define whether they're new; how we would separate them from equipment or supplies. And they're all variations—

Dr. Rapp: Could you give me some examples of what you're talking about—natural versus non-natural orifices. . .

Dr. Simon: Say, stents or grafts for example, those require a surgical incision in order to place. As opposed to—

Dr. Rapp: Are you talking about for end-stage renal disease, those kind of grafts?

Dr. Simon: Those kind of grafts, or if you put in a stent for someone, a cardiologist puts in a stent for someone who has cardio stenosis—

Dr. Rapp: OK, now is that a natural orifice, or a surgical orifice.

Dr. Simon: That would be surgical. As opposed to someone that may need a urethral stent, where the cystoscope is passed through the urethra into the bladder.

Dr. Rapp: OK, now what difference does that make? For your payment purposes?

Dr. Brazell: Currently, right now, only new devices that are inserted through a surgical incision are eligible for apply to potentially receive pass-through payment. That means essentially we would agree for a limited period of time to make a payment to a hospital at their charges

reduced to cost for that device, for their use of that device, recognizing that that device wasn't used in the past and wouldn't be reflected in the data that we used to set our payment rates.

Dr. Rapp: So if there's a new gizmo that comes along that Dr. Castellanos can put into the bladder through a cystoscope or whatever. . .

Dr. Brazell: That would not be eligible for payment through this—

[chatter]

Ms. Richter: . . . for a new technology payment if the entire procedure was new and wasn't adequately reflected in the hospital Outpatient Prospective Payment System, we could, we have two ways of dealing with new stuff. We have pass-through and we have new technology. And while they're not currently eligible for pass-through payments, they are eligible if the full procedure is new and not adequately described by any of our existing codes to be considered a new technology procedure and get paid according to a separate methodology for those. I don't want to leave you with the impression that there's no way to handle things that are pass-through natural orifices now, it's just that the pass-through methodology specifically is not accessible.

Dr. Rapp: So you're asking, first of all, do we think that there should be a distinction between natural and surgically created orifices for the purposes of this pass-through. Does it make any sense?

Dr. Gustafson: There is a distinction now.

Dr. Rapp: There is a distinction.

Dr. Gustafson: . . .by manufacturers asking us to discontinue it and to allow the separate payment for things coming in through your mouth or whatever.

Dr. Rapp: Do we have an opinion on that? Dr. Castellanos?

Dr. Castellanos: . . . so many minimally invasive things and you can't go by what we've done in the past. And I think you need to define the device, and not the way it's put in. And I think that's the easiest, simplest way of handling that.

Dr. Simon: What do you mean by that?

Dr. Castellanos: Just what I said. An incontinence device; whether I make an incision to do that or I implant a device I'm doing a clinical study on now, it's still the same type of device to be put in.

Dr. Simon: I think that tugs at one of the questions that Dr. Brazell raised as well.

Dr. Castellanos: But you're making it complicated—

Dr. Simon: Let me finish. If there's a variety of devices on the marketplace for incontinence, and then there is a new device that comes out that has not been proven to be better, then I think one of the questions is how should that be addressed in terms of the payment system as well.

Dr. Rapp: The first question is should there be such a artificial I suppose distinction?

Dr. Gaughan: I don't understand why there's a distinction. You're talking about hospital payments for the device, not physicians. Why it should make a difference how in the heck we put it in or not and how that affects the cost to the hospital and why they should be punished if I can figure out how to stick it through the nose instead of through the neck. It just makes no sense to me. If you're asking for my opinion as an Ear, Nose & Throat and also person who kind of knows what's going on in hospitals, I do not see the reason for saying you have to make an incision, and I can make an incision like that or like that, depending on what kind of surgeon I am, and luckily we don't have that much room. But to me, it's a pass-through whether you make a nick or you don't, and some of us, Dr. Castellanos and myself, usually go through natural orifices. And other surgeons, orthopedists usually have to make a little cut. It shouldn't, we shouldn't be punished, or the hospital punished because we can figure out how to do it through an orifice and the orthopedists don't have an orifice to put it in.

Dr. Rapp: I guess the summary is, unless there seems some obvious reason for such a distinction, it doesn't seem to make any sense to the doctors. How might a new device surgically introduce through an existing orifice be distinguished from older technology, also inserted

through an orifice? You're concerned that just automatically you're paying for the latest, greatest gizmo that may not be any better than the old gizmos? Is that the concern?

Dr. Brazell: When does it really become new, because clearly the devices are, and their use are reflected in hospital claims data and their charge data, and so are there issues around how we would decide if something were new?

Dr. Rapp: Does it matter whether it's new or whether it's better?

Dr. Brazell: Both, we would argue. I mean if it weren't new, and presumably it were better, it would maybe have been used and reflected in the hospital claims data that we use for setting rates.

Dr. Rapp: It's only new if it's disposable. It's usually not better, but it's new. OK, well we have to sort of go through this quickly. What distinguishes a device inserted through an existing orifice from surgical supplies? What distinguishes instruments that are supplies when used for open procedures? Is there any additional information you could email us and then we could distribute it to the Council and we could ponder this a little bit more? Because we're running out of time.

Dr. Brazell: Sure, we'll think about that, and any

Dr. Rapp: We don't have that much knowledge about this basic issue. And perhaps if you'd kind of summarize it a little bit more for us, we could email it around and you'd get some responses back. Dr. Johnson?

Dr. Johnson: You've got the Medicare coverage advisory committee, if you needed to on some of these new technologies, if you couldn't come to a decision. That advisory committee is out there.

Dr. Rapp: Dr. Urata?

Dr. Urata: I think the specialty committees that use these products would be helpful, too.

Dr. Rapp: Well, at least we answered the first question. And was, were there other questions? Dr. Leggett?

Dr. Leggett: You might want to add to your list, what I think is the more important question is what is the physician requirement training necessary to do orifice versus surgical insertion of these devices and how should the physician be compensated appropriately for that technology.

Dr. Powers: I have a resolution that goes back to the first question. I can give it now or later.

Dr. Rapp: Have you got it distilled? OK, pass it to Dana and then you can read it while she hears it.

Dr. Power: This should be fairly simple. PPAC recommends that Medicare provide to physicians a brochure simplifying the concepts of observation versus inpatient admissions in order to improve physicians' practices in admitting patients to hospitals.

Dr. Rapp: OK, do you have that Dana?

Ms. Trevas: Sure.

Dr. Rapp: Is there a second?

[Second]

Dr. Rapp: Read it one more time only a little slower for the Council.

Ms. Trevas: PPAC recommends that Medicare provide to physicians a brochure simplifying the concepts of observation versus inpatient admissions in order to improve physicians' practices in admitting patients to hospitals.

Dr. Rapp: OK, so that was seconded. Is there discussion? If not, all in favor?

[Ays]

Dr. Rapp: All opposed? That is agreed to. We'll now thank our presenters for an excellent presentation. I think an informative discussion and hopefully it was of some help to you. And we'll take a break now until 1:15, when we'll resume, for lunch.

H. LUNCH

Dr. Rapp: I'd like to call the meeting back to order. Our next speaker I think is caught in traffic for a couple of minutes, so I think there's a couple of additional recommendations people want to put forward, so why don't we spend the time we have to do that. First of all, Dr. Powers?

Dr. Powers: I would just like to reword the prior motion, make a motion to reword the prior motion.

Dr. Rapp: This is without objection.

Dr. Powers: Amend the prior motion instead of the word brochure, change that to [medlearn matters?].

Dr. Rapp: How does it read now? Prepare a. . .

[chatter]

Dr. Rapp: OK, so the medlearn matters is what the website has. All right is there any objection to that change? Seeing none, Dr. Castellanos?

Dr. Castellanos: I have two—

Dr. Rapp: It's so amended.

Dr. Castellanos: The first one is PPAC recommends that CMS discontinue the least cost alternative policies, as these do not comply with both Congress and CMS express desire to let market forces determine ASP prices.

Dr. Rapp: Is there a second to that?

[second]

Dr. Rapp: This least cost alternative. Can you explain what they're doing there?

Dr. Castellanos: Specifically I can talk about it in urology, but Barbara may want to talk about it. There are two drugs are basically the same, and they've been priced differently by the manufacturer, and I think there are about 37 states that fall under LCA alternative policies, as compared to about 13 that don't. So we're required to buy the least cost drug by our local carrier medical director. So what we're saying that is if we're going to be required to buy these drugs at the least cost that this really abates or obviates the spirit of MMA's decision to let market forces,

and we heard Ken Simon this morning talk exactly the same, letting market forces determine ASP.

Dr. Rapp: OK. Could you read that back?

Ms. Trevas: PPAC recommends that CMS discontinue the least cost alternative policies, as they do not comply with Congress's and CMS's express desire to let market forces determine average sales price.

Dr. Rapp: And that's been seconded I think. Is there further discussion?

Dr. Gustafson: Just to provide a point of clarification, Dr. Castellanos, the way the least cost alternative policy works, the physicians are not required to purchase one drug over another. The carrier in that area simply asserts that it will only pay at the lower of the two prices. So you can still furnish the other drug, but you're only going to get paid at the lower of the two.

Dr. Rapp: Any further discussion? Dr. Bergeron?

Dr. Bergeron: Discussion no.

Dr. Rapp: If not, all in favor?

[Ays]

Dr. Rapp: Anybody opposed? That motion carries.

Dr. Castellanos: I had another one, too. PPAC recommends CMS investigate the carriers' core application of the least cost alternative policies.

Dr. Rapp: Is there a second to that?

[Second]

Dr. Rapp: Do you want to explain that one?

Dr. Castellanos: There are several states that have implemented LCA policies and they've done it incorrectly. And then they send out letters of overpayment due to the urologists to try to make up for this. So there seems to be a lot of uncertainty among the both the carriers and the urologists and I think this puts a tremendous burden. Now, not every office is large enough to be

able to look and audit all the LH RH claims to overcome the carrier's inability to correct this payment problem.

Dr. Rapp: OK, is there discussion on this? Is this pertinent to the presentation we had today?

Dr. Castellanos: It's pertinent to LCA, yes, and it's pertinent to reimbursement and prices.

Dr. Rapp: OK. Discussion? All in favor? Oh, sorry.

Ms. Trevas: PPAC recommends that CMS investigate the carrier's poor application of least cost alternative policies.

Dr. Rapp: OK, any further, is there some discussion on this item? If not, all in favor?

[Ays]

Dr. Rapp: All opposed? That motion carries. So now we'll, is it a different recommendation? I was going to start with our presenters here. Then we'll go back to it, but we have a break at 2:45, and so prior to that, I'll entertain these other recommendations and any others so that hopefully Dana can get them together at that point except during the break.

Our next session will address promoting transformation and physician office quality. The speaker will be Dr. William Rollow. He's the Director of Quality Improvement Group at the Office of Clinical Standards and Quality, Centers for Medicare and Medicaid Services. He will share with us 3 initiatives which have been undertaken to promote transformational improvement in the quality of physician office care. Thank you, Dr. Rollow.

Dr. Rollow: I just talk and this works. What a deal! Nice to see you all. I am the Director of the group that has responsibility in CMS for what used to be called the Pro Peer Review Organization Program, now the Medicare Quality Improvement Organization Program, and what I'm going to talk to you about briefly today is some work that we've been doing that really began a couple of years ago and is now getting to the point where it's achieving fairly broad implementation in the next period. On promoting improvement in the quality of care that's

delivered in physician offices. We use in the slide, actually uses the word “transformation” to mean that when we started thinking a couple of years ago about things that QIOs were doing, and more broadly Medicare is doing, that impact quality in physician office care, we thought that although we were doing some things, and we had some measures that were showing some improvement, particularly for physician office care, there was the opportunity to do some things that might have very more substantial impact on measured levels of quality. So with that in mind, we began to think about are there some things that we could do that might promote really a transformation, a substantial change, in what quality would look like. And we thought that in order to accomplish that, we would have to do things that rather than leaving essentially the existing care giving process pretty much in tact within physician offices and instead having QIOs work just at the margins of the existing care giving process, that we’d rather think about are there some fundamental changes in physician office care, that would substantially improve physician office quality?

And with that in mind, we felt that there were really two basic ideas that we wanted to work on. One is that substantial improvements would require the adoption of health information technology and secondly that in addition to that, it would be important to look at major changes, redesign if you would, for certain aspects of physician office quality, or physician office process that would have an impact on quality.

So those were our two broad ideas; health information technology adoption, and office process redesign associated with that to yield substantial changes in quality. So go to the slide please.

So with that in mind, we thought about three things that we might do that would help advance information technology adoption and process redesign. The first to make high quality, affordable health information technology type systems available; secondly to provide assistance to physician offices in adopting HIT and in making process changes; and thirdly to offer financial incentives that would align the reward structures with those two things.

Those are the three things then that I'm going to talk about in 3 slides.

On the first, making systems available: As we looked a things a couple years ago, we were interested to find that although there were a variety of products, health information technology products—EHRs, Registries, E-prescribing systems, etc.—although there were a variety available and many vendors, many products available in the market, for the most part, they didn't really have the quality that was needed, the functionality that was needed in order to substantially improve physician office care. Some of them did. Some of them had pretty strong functionality, but actually most of them didn't and really had been designed for other purposes, sometimes to improve documentation, sometimes to improve revenue generation, sometimes to ease some work flow inefficiencies, and although those things are desirable, they don't by themselves get to what we were aiming at, which was higher levels of quality.

Additionally, the systems that were available that did have pretty good functionality were quite expensive, and by quite expensive I mean easily per physician, it was possible to spend $20, $30,000 alone just on software on an annual basis. That's too much money. So we thought about things that we might do, this is going back a couple of years, that might change the availability of products. Our primary strategy was that we should do things that potentially would stimulate the market to offer those products; to improve their functionality and to improve their affordability. And the first step that we took on that was to try to, in conjunction with work that we did with others, make available a better framework for understanding the functionalities of the different systems. So you could look at this just as a descriptive terminology. You could look at it as a set of recommendations about what good systems would do. Either way, we in working with Leapfrog, with the Institute of Medicine, and with HL-7, HL-7 ultimately doing a standards development process on this, we sought to make such recommendations, or such a descriptive framework available.

This has become the forerunner now of an activity that has begun this year in the private sector in the form of a certification commission for health information technology. The CCHIT.

Which will take some of the work that was done earlier and turn that work into a set of systems certification requirements or standards, and then will actually certify health information technology systems, EHRs, registry systems, and E-prescribing systems, such that by next year, roughly mid-year, is the time that that group is anticipating, when a physician office looks to purchase a system, they'll be able to look for a seal of approval, they'll be able to understand based on that, that the system meets certain standard specifications for it's ability to operate, etc. Additionally, this sends a pretty significant signal to the developers, to the vendor market, about the kinds of systems and the kinds of functionality that they should have in those systems. So that was one way that we sought to make systems available.

Another way was more direct. And that has been we are engaged now in a project with the Veterans Health Administration, with the VA, to create a version of the VA's electronic health records system, that would be available for use in small- and medium-sized physician offices. The VA's system, which is Vista, has very high levels of functionality. It's a very powerful system and in the VA setting, it works very well. It doesn't work very well outside the VA setting, but it's possible for it to do so. And so really over the last year, we've been underway with a project that should, again, by the middle part of next year make a version of the VA system, it would be called Vista Office EHR, available for use in small- to medium-sized physician offices.

So that's the kind of thing that we've been doing on the systems availability side. I should probably add on the Vista thing by the way that although some physician offices may want to just pick that system up directly and put it on their computer and run it, for the most part, we don't expect that that'll be the use of it. For the most part we expect that the use will be other developers will pick it up and offer application and support services such that a physician office can pick it up for a much lower price than if the developer had to pay the development costs for an electronic health records system.

Let me move to the second of our initiatives. We've been underway with a project called Doctors Office Quality-Information Technology. The DOQ-IT Project for more than a year now. This project aims to develop a methodology that QIOs can use in providing assistance to physician offices. The lead QIO here is the California QIO, La Metra. And La Metra has been working in conjunction now with three other states, Arkansas, Massachusetts, and Utah, to create a four-state pilot, which is underway, has been since the spring, in which in these states, first of all La Metra has invested heavily in developing this assistance methodology, and now in California and the other three states, the QIOs are piloting it with a set of physician offices. The assistance really aims to do three things. It aims to help physician offices make the adoption decision, adopting HIT, helping them take a look at the needs their office has, and whether or not health information technology and process redesign would help them meet those needs, what the cost in benefits would be, what kinds of systems are out there, what the costs and value of those systems might be; so it helps them make not only the adoption decision but selecting an IT system, and also doing some of the initial planning work to begin that process.

The second component of the assistance is at the time of implementation, when a physician office adopts health information technology, along with the support they're getting from typically the vendor that sold them the system, they're looking to put into place work flow efficiencies, changes in the way they do transcription, changes in the way they do medical record pulls, lab ordering, pharmacy ordering, other kinds of process changes that can have an impact n efficiency and so that's the secondary effort for the QIO to help them.

And then the third is having done these things and presumably having achieved some of the efficiencies, physician office is then helped with measuring clinical quality, using a set of clinical quality measures that's currently going through the NQF process, the set that CMS worked with the AMA in the development of and then additionally redesigning care processes; putting in care management, putting in patient education and self-management processes, to enable a physician office to better take care of patients with chronic illness and to do better on

these clinical quality measures. So that three component assistance methodology is being piloted in the four states. QIOs have now more broadly begun to be trained on this methodology, and there's now actually a national pilot underway in each state. QIOs are working with a very small number of physician offices to pilot this methodology. We expect that it will be available more broadly in the 8th scope of work. The 8th scope of work begins in August 2005. And although we're currently underway in our discussions in the department in OMB on funding for that program, we've proposed that this methodology would be available by all QIOs in all states beginning at that point.

And this is the third and my final slide, coving these types of initiatives. The third thing that we thought we might do is to seek to provide financial incentives for health information technology and for improving the process of care and therefore improving care on clinical measures. We were fortunate in that as we did the work of preparing what Medicare can do, which is a demonstration in this area, the Medicare Modernization Act came along, and in working with one of the provisions of that, we've ended up with Section 649, which mandates the Medicare Care & Management Performance Demonstration. It's a four-state demonstration. We're expecting that, hoping that, these four states would align with the four states that we've been doing our piloting work on the DOQ-IT methodology. And in that regard, in these four states, physicians offices then would be eligible for additional payment if either they demonstrate the adoption of health information technology or care management, self-management process changes, or if they demonstrate that they've done, they've hit target levels of performance on clinical quality measures. It's a two component to the reimbursement methodology that we're proposing. Here again, we're in the process in finalizing this demo with the department in the Office of Management and Budget, but we expect that the demo will look much as I've described it. Actually, we're aiming to have it work very closely with the methodology that the Bridges to Excellence Program private sector program would have. Bridges to Excellence developed out of the work that Leapfrog did a couple years back with CMS and with our ARC. They developed

Bridges to Excellence. We've been developing this program. So what we're looking to have is a public and a private sector program that fit together well, such that for practicing physicians, what they see is essentially one set of requirements and one way to fulfill those requirements as a result of which additional payment would be available. So we're hoping to get this thing launched in mid next year. That's our plan. It will be a 3-year demonstration project and that then covers I guess the third of the three activities.

Questions that I have for you all is: I've talked about things that we're thinking of doing. I'm interested in your reaction either to whether we've correctly understood some of the things that might need to be done that would promote substantial change in physician office quality, are the barriers that we've been aiming to try to address through these projects, things that you see, or are there other things that we as well should be considering? Do you think that the approach that we've got here is useful? Do you have suggestions for us about how we would implement it? And are there additional things that you think we should consider doing?

Dr. Rapp: Thank you. Dr. Powers and then Dr. McAneny, and Dr. Johnson?

Dr. Powers: I appreciate the approach that you've worked with DOQs all along with this, and we've been able to have our input from the beginning. And I do appreciate that and I appreciate your thoughts about offering financial incentives as things go, right now, the major barrier to adoption of IT is cost. And unless that changes, it will be difficult for us to comply with that 8-year plan to have all offices computerized.

Dr. Rollow: I say typically that every time I talk about this project, at least one part of the conversation is always consistent, and that is the recognition in the statement back that we've got to get the reward structure, the financial incentive structure right to be successful so I appreciate that comment.

Dr. McAneny: I also appreciate the work that you're doing in this and I think it's critically important, having bought the wrong EMR the first time, let me tell you it's more expensive to do it right the second time and the records need to be searchable. But one barrier that

I think needs to be considered and hopefully CMS can help physicians with this is the potential increase liability that is going to occur to physicians when they start using the data that they can get out of the searchable medical record to look at variations in care. If you are trying to do a quality project and say I'm going to make sure that 95% of the cases that I treat with X have this outcome, then you're going to have some people that are outliers. And as we've been trying to institute a quality project in the office to look at inadvertent errors, the problem with looking for errors is that you are likely to find some. And if you're like to find some, hopefully you can correct them before they have any clinical impact on the patient. But we live in a litigious society. So one of the concerns that I have that I see as a major barrier to care is that if you ask people to start doing the Leapfrog type questions and doing all of those that you will find errors and most physicians would rather not find the error and have the risk of liability for that error than to find it, even if you have a system to correct it. So if CMS could help us with some sort of guidelines. Get your folks, your friends at the OIG or anywhere else you like, to give us some guidance on can we use our lawyer to make this confidential information, can we call it peer review, and make it protected in some way, so that when we institute these quality processes, we're not painting a big target on our chests.

Dr. Johnson: Certainly the

Dr. Rapp: Sure, go ahead.

Dr. Rollow: So I think the liability issues are very significant actually. And it strikes me, first of all, your suggestion about maybe protecting in some way, the information is an interesting one to think about. I'm just going to say this and then see what you think of it. I think the IT world is going to make the liability environment only worse, and in some way, it's not a good environment to start with; there are too many things that potentially about the way the system works today, don't really help people figure out how to do a better job in a way that doesn't cause them to put themselves at risk. I think aside from the suggestion that you made, there's a much bigger picture here and I think the IT world is going to hopefully force all of us to take a look at

the bigger picture and think about how to do things in some significantly different way. And so I say that back just to in some sense suggest that I think we're going to need some broader policy considerations as we get more and more into IT-based care.

Dr. Johnson: Certainly one of the barriers is going to be the availability and the cost aspect, and having worked with the carrier in Florida for some 12 years in looking at electronic medical records, and one of the things that you come up against is the, we talked a little bit about this morning on some of the templates. If you can come up with good templates, but how do you keep that from being cookie cutter style. And then getting there to where the carrier wants things to be personalized, as opposed to having something there and dealing with template, so that you can quantify and qualify the record being individual, and then you're running against trade association's, in setting a "standard" that's out there because of not wanting to alienate membership. So what you're doing, I think, is very very good, that you're working with the public, private, and coming up with a standard, the cost aspect of developing some of this is a private entity, and then being able to say, well, is it going to be received? So I think some of those hurdles and the way that you're going about this in trying to promote substantial transformation, I applaud you, because it has been a barrier that you can't seem, as an association, working with the carrier and dealing with electronic records and also the confidentiality of it, if you're out there in cyberspace and trying to communicate back and forth with a carrier, these are big issues. Thank you.

Dr. Rapp: I have Dr. Azocar, O'Shea, Grimm, and Urata.

Dr. Azocar: I applaud. There is no question that this is going to be an influence, a good influence that's going to improve health care, but also it may have some additional benefits. For example, one of the costs for primary care practice, significant costs that we go from 8 to 10% is what I call billing. And this implementation of the electronic thing may facilitate and may reduce the cost of billing. I think that's an advantage to be explored. Having a direct experience in this process, I think that I have found one of the main issues is when you have to download the

information from records, especially when you have patients with considerable, with a big chart, and you have to load that, that may be an area to bring some help and encourage practices to adopt this system.

Dr. Rollow: I would just say in that second component of assistance, one of the important areas is working on some of the workflow efficiencies and typically that is what causes physician offices to make the adoption decision. And I think a couple of the commenters are right. There are some failed adoptions and that is obviously not what we're aiming for. The successful adoptions do ultimately result in improved efficiencies and reduced costs from some of these other processes, so thanks, that's a good point.

Dr. O'Shea: We can see the writing on the wall, it is coming at us. And we do think that through trials and bleeding errors that it's going to improve our practice. I look forward to experiencing [?] because I'll be part of it. So I'll be able to come back to the committee with some reporting. I hope that duel trial has been put onto this VA system and that we know that Vista A is the right thing to work off of, because there are many things, as with billing, as with being able to contact pharmacies as we've able to schedule, if everything could be put onto the same screen, and at the same time have the flexibility to put the art in the medicine, and that's really what we're still looking for so that we're not cookbook practitioners, and also the efficacy of communicating safely, because I think that's also part of what Leapfrog and other carriers wanted, that when one patient went to another provider's office, whether it was a hospital or a different level of care, that the access of prior history would be available to them so that things wouldn't have to be done over and done over. So we're really looking for a huge system, I see that. When you said we're waiting for a developer, the other part of that is not just a developer, but the vendor. So we want to make sure that who's ever going to vend it is going to be a reputable source for us to use from.

Dr. Hollow: Actually, a couple more thoughts on the Vista Project. One thing to be said is we don't expect to have most physicians adopt a Vista product. It's just an option out there in

the market. It's valuable because it's high quality and it'll be quite affordable, and therefore it'll set a pricepoint for a certain level of performance that then stimulates the market, other developers, to offer products of similar functionality and affordability. But even so, we want it to be an effective product and so it may be useful to let you know that actually the development work should be complete in January. We won't release the product for about 6 months after that because it's going through several rounds of testing and so an absolutely, the kinds of functionality that need to be incorporated include interfaces with billing systems and a number of other things that really aren't the issue, lab interface, aren't really the issue so much for the VA system. Now, the lab interface, actually is an issue for all electronic health records systems at this point, and so one of the things that we're doing through the project is seeking to stimulate the development of a standardized lab interface, that all systems could use and as a result of that, all labs and developers could take advantage of. Thanks again.

Dr. Grimm: . . . four to five years. . . observations in how it works practically in a physician's office and individual centers, not only in the United States but around the world, so I'd like to share a few of those things that I've seen that I've seen that have failed, things that have been practical. But a few basics here, and of course what you're doing now, is your stepping out the format which people will work around and try to work towards. So I think it's very helpful for you to set out an outline for them and help them fill in the gaps. And just a few things. I think all personnel need to be involved in QA. That means all members of the team in any kind of center you go to. These are probably things intuitively you know already or have worked out. But they need to be objectively based and respect the standards, and I'd encourage you not use the word "best." Best always is going to put you in a situation where it's never going to get an answer. Just put what is respected, what is acceptable, and then you're always work towards better, but you'll never find "best." It has to be practical and efficient for doctors, so they can implement it on a daily basis, you have to have immediate feedback. If you don't have immediate feedback, you cannot change performance. And behavior. That's true in all levels of business, so

I think that has to be there. There has to be whatever measurement tool used, it has to be demonstrable improvement by using that tool. You have, where you are now, where you were then. I'm just outlining things that I've learned. I agree with Barbara completely that it has to fall in some sort of QA protection. So there has to be a peer process, because we found in our first, when we started doing it, that the first time is very painful for centers. They find that they're doing things incorrectly. You've got to give them an opportunity to change without penalized. And it has to be, as you said, incentive based. It's got to be a financial incentive here, to do it. Those are sort of the basics and I thought I'd just give those thoughts.

Dr. Urata: When you have an electronic medical system, you're setting yourself to be hit by a whole bunch of different people. Our hospital, I understand from our IT people, even though we're a small hospital, we get over 250 hits of people trying to break into our system and viruses and things like that. And in a small office, that's kind of a—you almost had to have an IT specialist on staff or have access to that. Also, would HIPAA apply to this, too if somebody broke into our electronic medical system? I mean we could be responsible for a heavy fine under HIPAA, as I understand it. And so I think that's a barrier that. I think it's good that we're heading that way, but I think that's another barrier to slow us down in terms of attaining that.

Dr. Rollow: So I think what you're asking actually is it would be useful to have some guidance about what kinds of security considerations need to be involved when a physician office is putting up an IT system.

Dr. Urata: And even though you have the standards of security, there's a possibility that somebody's going to break in. And if so, you're still ultimately responsible and you could be facing major fines from the government because of the HIPAA Law. And that's a financial, that could be a major financial hardship looking at what the hospitals are going to be responsible for. If they're computer system gets broken into.

Dr. Rapp: OK, Dr. Johnson?

Dr. Johnson: Has anyone from the state of Florida, the Florida Senate or so contacted you about electronic medical records and development? The reason I'm asking is there's an initiative that's underway with the state of Florida looking into a model on electronic medical records.

Dr. Rollow: Developing?

Dr. Johnson: Having a task force that's going to come out and make recommendations or so to them and certainly, I'll make recommendations to some of the people that's involved with it that they get in contact with you.

Dr. Rollow: Yes, if you know somebody, that would be fine.

Dr. Power: Resolution #1. PPAC requests that DOQ-IT work with the Office of the Inspector General, to find measures that can legally protect the information gained from quality improvement activities.

Dr. Rapp: Is there a second to that?

[Second]

Dr. Rapp: Can you elaborate on that a little bit?

Dr. Power: It goes back to what Barb says. If we're going to do quality improvement, it will be hard to get people to do that if we think the information is unprotected. It needs to be protected just like peer review.

Dr. Rapp: OK, so PPAC recommends that, as opposed to requests.

Dr. Power: That DOQ-IT work with the Office of the Inspector General to find measures that can legally protect the information gained from quality activities.

Dr. Rapp: Just for my curiosity, is the Inspector General the appropriate body within CMS to work with for something like that? All right, could you read it back?

Ms. Trevas: PPAC requests that DOQ-IT work with the Office of the Inspector General or General Counsel to find measures that can legally protect the information gathered from quality improvement activities.

Dr. Rapp: That's been seconded. Discussion? All in favor?

[Ays]

Dr. Rapp: All opposed? That motion carries. And was there a second motion?

Dr. Powers: PPAC requests that DOQ-IT provide guidance for levels of security needed to avoid infractions under HIPAA.

Dr. Rapp: Is there a second to that?

[Second]

Dr. Rapp: Read back please?

Ms. Trevas: PPAC requests that DOQ-IT provide guidance for levels of security needed to avoid infractions under HIPAA.

Dr. Rapp: Any discussion? All in favor?

[Ays]

Dr. Rapp: Going to have to give you all a cup of coffee. . .

Dr. Gaughan: Did you mean physician protection on your first recommendation?

Dr. Powers: Yes.

Dr. Gaughan: Because I don't know if that's clear.

Dr. Rapp: Let's vote on the second one. We're not talking about the second one yet. All in favor?

[Ays]

Dr. Rapp: Anybody opposed? That passes. I was in the middle of getting the nays or trying to see if anybody really said anything. OK, the first one, what did you want to change?

Dr. Gaughan: No, I'm just asking Dr. Powers if it's clear that it's physician liability.

??: Friendly amendment to put physicians in there to make sure that we know that we're protecting physicians.

Dr. Gaughan: We're glad to protect CMS, but. . .

Dr. Rapp: Does our reporter know where that goes?

Ms. Trevas: PPAC requests that DOQ-IT work with the Office of the Inspector General or General Counsel to find measures that can legally protect physicians when information is gathered from quality improvement activities.

Dr. Rapp: Is that changed how you want it?

Dr. Gaughan: Is that what you wanted?

Dr. Powers: That's fine.

Dr. Gaughan: I just wanted to clarify it—

Dr. Rapp: Is everybody OK with that? If there's no objection than it's changed that way. Anything else on this subject? If not, thank you very much Dr. Rollow. Dr. Bergeron had a proposed recommendation, as does Dr. McAneny, so I'll take 2 minutes between speakers to try to deal with those.

Dr. Bergeron: This may be moot because the project may be cut in stone, but if it isn't, PPAC recommends CMS look into alternative demonstration projects to ascertains the rewards, cost-sharing, to CMS Medicare recipients, [?] can justify the expenditures of $300 million. This is in reference to the present $300 million demonstration project concerning cancer patient treatment side effects assessments, etc.

Dr. Rapp: OK, do you have that written down for our reporter? Is there a second to that motion?

[second]

Dr. Bergeron: I would like to discuss basically, I'm under the impression that when a physician treats a patient, that one goes on follow visits and automatically like, for instance, Acutain in our office, which is retinole, a patient comes in and we have a check list. As a matter of fact we have a checklist that's comprised of 16 entities we check, not only four, including nausea, vomiting, headache, CNS symptoms, visual, etc. And in our office, that's included in the office visit. We get no special reimbursement. This to me is just basically practicing medicine. You give a patient a medication, you come back for a follow-up visit. You question, you're going

to spend $300 dollars to ask then whether or not we're going to go on and pay physicians questioning patients who are being treated with chemotherapeutic agents and therefore can be reimbursed an additional $130 per office visit. I can't see the rational behind it. If we have $300 million to spend, fine. If we're going to get the bang of our buck, fine, but I can't see it.

Dr. Rapp: Is this discussion on the motion?

Dr. McAneny: I'm going to vote against your motion and the reason for that is this is a different entity than that. This is not what we do in a routine office visit where we always ask that. One of the things that come up in trying to set up the reimbursement for infusion of chemotherapy is that we have set up systems in the office to make sure that we talk about those patient symptoms that are being mentioned in this. So one of the issues that CMS is trying to do here, I believe, reading what they said in the *Federal Register*, is to try to document that we truly actually do all of those things that we claim to do, and that we don't do them in the context of an E&M-Code. When I see a patient in the office and do an E&M-Code, I bill that E&M-Code. This demonstration project is when the patient comes back in the next day or the next week, or over several days in the following week to be able to get their chemotherapy and I'm there in the office to supervise them and we do a lot of those kind of things on the fly. So the purpose of this demonstration project is for CMS to have us, as oncologists prove that we actually do all of those other symptom managements that are outside of the E&M-Code.

Dr. Bergeron: Well, isn't that the normal course of treatment when someone comes in who's being administered systemic drug to ascertain whether or not any side effects—in other words, to me, if I had these patients, and [?] to have a patient come in and go in for a follow up visit, well what does my follow up visit consist of? Evaluation—your acne's improving, and subsequent, have you had any headaches, etc. We will continue or discontinue the medication. We get lab work, we do the whole gamut, and yet we charge, specifically a basic office visit. I have a little difficulty as an addition to your basic office visit, charging $130 in addition to

ascertain whether or not they have any side effects from a medication you have administered to the patient.

Dr. Rapp: Could our reporter read the resolution?

Ms. Trevas: PPAC recommends CMS look into alternative demonstration projects to ascertain the rewards-cost-sharing to CMS-Medicare recipient will-can justify the expenditure of $300 million. This is in reference to the present $300 million demonstration project concerning cancer patient treatment side effects assessment.

Dr. Rapp: Is there further discussion on that?

Dr. Castellanos: If indeed, this is why CMS is doing this project, and I believe her, because that's what's in the *Federal Register*, why not include it to other physicians who treat cancer, not just by push or infusion, but to include subcutaneous, intramuscular and surgical implants. These patients have the same problems as the patients that are getting push or infusion. So in the spirit of getting this data, I think a wide variety of patients include subcutaneous, intramuscular, and surgical implant should also be considered in this one-year demonstration project.

Dr. Rapp: This is discussion. We've got a motion. Dr. O'Shea?

Dr. O'Shea: If I remember Mr. Thompson's statements, they were trying to do this in response to a patient's questions or their admissions that there was a lot of post-chemo reaction going on; I think it's for documentation. I think again, it's just a project that could go on for a year for documentation on certain side effects, and what we're going to glean from that is hopefully at times of interactions, times of mal effects, and he also said to try and decrease the ER visits. So in a way it's trying to be a cost-saving measure only again, as a research project for that one year. It does seem like a large pricetag. I agree with you it's a large pricetag, but I think it's for a certain outcome. And I think that this is a specific population that's receiving chemo drugs just for this one year to do that, so I would have to agree with Dr. McAneny.

Dr. Bergeron: And then you practicing physicians tell me that all systemic medication will get patients who not have side effects, so therefore we shouldn't question the patient, and if we do, we get an additional fee? I have a little difficulty with that, especially when a $300 million tag. That's just my opinion, thank you.

Dr. Rapp: Is there other discussion on this? If not, all in favor of Dr. Bergeron's motion, said Ay.

[Ays]

Dr. Rapp: OK, raise your hands so I see who's voting for it. One, two, three, all opposed? All in favor again? Hands up please, one, two, three, four, five? [chatter] Four. All opposed. One, two, three, four, five, six. The motion fails. OK. Sorry for the delay. But we're trying to get these recommendations in rather than use every available minute here. The next item for discussion will be Medicare Preventive Benefits, and we have here Dr. Marcel Salive, Director of the Division of Medical and Surgical Services Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare and Medicaid Services. Dr. Salive will share with us the new preventive services relative to the Medicare Modernization Act.

Dr. Salive: Thanks for inviting me. My first talk, I have two talks, and the second one will be on coverage, after the break. The first is on Medicare Preventive Services.

So the Medicare Modernization Act provided for three new preventive services. Unlike therapeutic and diagnostic services, which are covered by the Social Security Act, each new preventive benefit has to be put through Congress. And so these were three that came through last December and I'll be talking about how we're implementing them at CMS today. And the initial preventive physical exam is commonly talked about as the Welcome to Medicare visit. That's what everyone is calling it. It's got some traction. It sounds much better. But I'll also be covering the cardiovascular screening blood test and the diabetes screening, and those were put out in the Final Rule last week, that's about the size of the phone book.

Dr. Rapp: It was 867 pages?

Dr. Salive: It's in there somewhere. But they go into affect.

Dr. Rapp: But it was double-spaced.

Dr. Salive: I have the double-spaced version myself, but only selected parts. But that goes into affect in January, so I think it's a very good time to talk about this. We had one question that we wanted to get your input on was about how to encourage people to take advantage of the new benefit, given this kind of time frame that we're under, and I think that's what I want to focus on but I want to first focus on the benefits themselves.

So the Welcome to Medicare exam is just that. Within the first six months of enrolling in Part B, a preventive exam is done and I think the intent really is to deliver clinical preventive services that are accepted and effective in helping keep people healthy and reduce the burden of disease whenever possible, so doing that, right up front at the beginning of Medicare, and then coordinating with other preventive benefits and kind of laying out a plan for those other preventive benefits over time, going forward with the patient. So I think it's a very nice package.

And it has some components. We've tried to flesh it out a little from what the Congress put into the legislation, but not too much, but I think it's fairly reasonably structured. We did get a lot of public comment that we took into account in developing the Final Rule and certainly it includes a medical history and social history. The focus there is really on attention to modifiable risk factors for disease. We talked as well about some of the major issues that occur in this period of life, such as depression, functional ability, home safety, the exam of course is there, but we have not really specified many elements of that. An EKG is included, and there is a written plan and some discussion and counseling about the future age-appropriate screening test.

And so the medical and social history with this focus on modifiable risk factors talks about the past history of medical illnesses, surgery, typical common things that people find out. This of course can be abbreviated if it's a patient you've had for a long time. I think we want to focus on things that are modifiable. Medication is certainly important, family history of tobacco, we thought was a very important thing to talk about in this setting, other drugs. Talk about diet,

talk about how much physical activity people are getting and depression screening can be done with a standard tool or with an appropriate questionnaire that's recognized by one of a number of professional societies.

So some of the components that we have included are screening for hearing impairment. This is really kind of a questionnaire kind of thing, or questioning, screening, not any kind of technological screening. This is then recommended by the US Preventive Services Task Force, and has a strong evidence base to question people and then make referrals to other evaluations when appropriate.

Activities of daily living. Certainly functional status. It's good to get a baseline of that on a new patient. The falls are certainly a public health issue in the older population. This is in line with the US Preventive Services Task Force as well about if things are noted that raise the risk of falls, to provide counseling in this visit about specific measures that can prevent falls. And as well, a little bit of discussion can occur on home safety, such as preventing household or recreational injuries. The physical exam. The language in the law required height, weight, blood pressure, and the EKG. We also felt it important to add visual acuity screening, and we did not make any kind of specification of that, although I think the US Preventive Services Task Force recommends the use of the Snell Eye Chart. Other measures may be appropriate, depending on the history of the patient, certainly and what may be focused on.

So at the conclusion of the exam, there's education, counseling and referral briefly on things identified from the history and the exam, and we did specify a written plan, although this can be a checklist kind of approach, to further services, preventive services that are indicated for the person. So this would promote and I think encourage further participation by the person in their own health care in becoming aware of the Medicare benefits that they're now eligible for and so on. And we encourage the use of a timeline. When these would be conducted.

So that's kind of it in a nutshell in the Welcome to Medicare visit.

The other two screening, I'm going to cover the diabetes screening test and then the cardiovascular screening tests. Unlike the other two, the diabetes screening test is more narrowly focused to people at risk to diabetes so it's not really for every Medicare beneficiary, but it's more targeted. It includes a fasting glucose and other tests which the Secretary may determine appropriate. We specified in there the possibility of using oral glucose tolerance test, or a two-hour post-glucose challenge load. And then the frequency also can be based on the risk of the patient. So someone who is pre-diabetic, which we define in the Rule, could receive 2 screening tests per year, and others who are eligible could get one test.

In the cardiovascular screening test, we specified essentially lipid panel of total cholesterol, HDL, and triglycerides, covered once every five years. And the possibility for both the diabetes screening and the cardiovascular screening is so we could add other tests through the national coverage determination process. And I'll be covering that in my second talk, what that process is. But essentially, it's an evidence-based process.

The cardiovascular is fairly consistent with the recommendations of the US Preventive Services Task Force, which deals with routine screening of those above age 35 for men, and above age 45 for women, and recognizes that it's screening with intent on treating those who are at higher risk. The task force recommends the total cholesterol and the HDL. They did not find sufficient evidence for or against triglycerides.

We chose a frequency of over 5 years for the cardiovascular screening because this is consistent with the US Prevent Services Task Force. It's also consistent with the NIH cholesterol education program, ATP2, which was endorsed by the Heart Association and it's also similar to their follow up ATP3 recommendations. And there is not a great time change of Lipid levels in the older populations, and that's essentially the basis for this kind of frequency.

There is of course some coding and payment that goes along with this. Hopefully my colleagues can pitch in and talk about this. But there was a new HCPCS-Code for the initial preventive exam, a certain work value was come about, and it does not provide a waiver for co-

insurance, since it becomes at the beginning of someone's enrollment, is of some note. There is the possibility to bill and be paid separately for the screening EKG and then a if in fact during this preventive exam other diagnostic or therapeutic services were indicated, there's a possibility for billing a more extensive office visit at the same time, although in the logistics of the office, there may be some realities setting in there. As long as those services are medically necessary.

For the cardiovascular screening blood test, we used the special screening code, ICD-9 Code and there's a similar code for diabetes, special screening for that, and these payments are the same for the blood test screening as for diagnostic use. They will be free.

So this went on display last week and those are my contact information, just FYI. So we do have a number of plans for disseminating this information, certainly presentations like this, the website, forums, conferences. There's a couple of plans for a Medlearn Matters article. Factsheets. We've had a couple of press releases already on the Welcome to Medicare visit. There's the Medicare and You handbook, that's being revised for the 2005 for the beneficiaries, which includes these new benefits, and a revised booklet on Medicare's preventive services. There's a two-page beneficiary brochure being developed, and that will be put into multiple languages.

Dr. Rapp: OK. Thank you. I would like to acknowledge that the American Speech Language Hearing Association submitted, I believe written testimony—I don't believe there's any oral testimony. So that is in there. But let me just ask you about that. They're recommending rather than this screening, basically just asking are you having trouble with your hearing, that people be given a specific audiometry test and I know that wasn't included but let's say the patient said, I can't hear so well, doc. Then, would Medicare cover the referral for a, would that be considered now the investigation of a disease if they say I don't, I can't barely hear?

Dr. Gaughn: Currently, you cannot get paid for as an EMT for a diagnosis of hearing loss or an audiogram, you cannot perform for hearing loss. You can perform for tinnitus. There are certain diagnosis but Medicare will not pay currently for hearing loss. And my other comment

was screening for hearing impairment; all the commissions for the deaf and hard of hearing have taken the work “impairment” out and it is considered an affront to the deaf and hard of hearing, and so I think to keep with the language I would say screening for hearing loss, since you’re going to Gallaudet University and a few other people upset. I noticed it’s visual acuity and that may seem silly to you, but when you sit on these commissions you won’t think it’s silly and when you get comments from your deaf and hard of hearing – so I would call it springing for hearing loss and I also wanted to ask Dr. Rapp a question, because if we’re going to screen these patients and then say, OK, now you need further testing. But Dr. Gaughan you said I needed further testing and now it’s not going to get paid for an audiogram is about an $85 test, so I think that’s a good question.

Dr. Salive: Well, you’re right. I think that that’s the current stay of play for the coverage of those services, that they’re not covered when they’re going to be used to determine the need for a kind of hearing aid.

Dr. Gaughan: It’s the other kind of hearing can be [?] there can be other causes of hearing loss other than I need a hearing aide, [?] should see a physician for hearing loss and that should be covered. People aren’t coming and saying I need a hearing aid [?] coming into your office and getting a screen. So, now would you cover the vision test if they have vision loss?

Dr. Salive: I’m not 100% sure on that.

Dr. Gaughan: I’m just concerned because these poor doctors find someone to screen and then they send them, they’re going to get a call saying, $85, and you told me to go. So I think it’s a great that Medicare is screening and using the screening tests that are inexpensive as [?] fill out, but then what are we supposed to tell the patient?

[chatter]

Dr. Gaughan: You look at the other test and you go limp, yes I can get a diagnosis. I look at the other test diabetes. Yes, I can get paid for that. I didn’t see anything up there other than I’m

not sure of the visual acuity that doesn't get covered by Medicare. And I applaud you for screening for hearing.

Dr. Salive: Well, we don't cover home visit for home safety. There's plenty of things in there that are not—

Dr. Gaughan: You can counsel for home safety you can't counsel for hearing loss until you have the test. You counsel for home safety. You need a walker. Get rid of your rag. I'm please you're doing this. I'm thankful you're including hearing.

Dr. Salive: I think everything has some financial impact on people, too.

Dr. Gaughan: I just wondered if you were now leaning toward covering hearing testing. Which I know would be a major budge problem.

Dr. Rapp: Dr. Bergeron, Dr. McAneny, Dr. O'Shea, Dr. Urata.

Dr. Bergeron: Dr., this is a point of information. I'm a dermatologist. I see a lot of Medicare aged patients, and some of them, they've never had another physician besides myself. And we've done initial when they come in, the history physical, etc. And I've had a couple of them say, well, Dr. Bergeron, I've been in the Medicare coverage for the last 5 or 6 years, I'm not new. But then the 6 months have passed. Will they qualify for the Welcome to Medicare visit if I should refer them to their interns. They have no other physician except me. I've been seeing them for their skin cancer, skin problems. And sure we've checked the blood pressure and occasionally this, but will these patients qualify?

Dr. Salive: The qualification is they are, they just joined part B within 6 months.

Dr. Bergeron: That's it, period.

Dr. Salive: That's it, yes.

Dr. Bergeron: Even though they're 76, and they have no other physician except myself.

Dr. Salive: Yes. Right. Well, that was in the law, so we. . .

Dr. Rapp: So it's part B, not part A. So there's something, you don't necessarily enroll in that at 65 if you don't want to.

Dr. Salive: Right, it's when they enroll.

Dr. Rapp: The next is Dr. McAneny?

Dr. McAneny: In the *Federal Register*, it said that there were 200,000 new Medicare beneficiaries monthly. And I'm just wondering whether or not, 2 things; whether CMS has done any work force types of studies to see whether or not there are enough primary care physicians in the country to continue providing all of these services to everyone who requests one. And then my second concern is if someone goes and gets their cardiovascular tests done in New Mexico and then moves to Louisiana and says, gee, I'd like to get that done, how will the second physician have any clue that someone already had their screening benefit, and is not eligible for a second one? Is Medicare going to somehow alert people to this so that they don't go to a second Medicare visit and spend all that time and get ding for it?

Dr. Salive: The, what was your first question?

Dr. McAneny: Do we have a workforce estimate for 200,000 new Medicare beneficiaries, per month, according to the *Federal Register*.

Dr. Salive: I guess our sense is just that given the large volume of physician services, this is a very small sliver of that. We felt—

Dr. Rapp: Are there enough doctors to do these tests is the question.

Dr. Salive: Our belief is that this is a primary care kind of visit and it's doable by a large—

Dr. Gustafson: I think it would be reasonable to suggest that a fair amount of this care or care of comparable nature is going on as is, and one thing that's happening now is Medicare is now picking up payment for these activities, where previously it didn't used to do so. Insofar as that is the case, there's not a supply issue.

Dr. Rapp: What was the second part to that?

Dr. McAneny: The second part is if the [inaudible]

Dr. Salive: Our feeling was that the issue was certainly prominent for the cardiovascular blood screening where the 5-year window is there. The possibility to give beneficiary notification that they may not be covered is open to the physician to give that KBN to the patient well may end up having to pay for it themselves. I think our feeling with the Welcome to Medicare with the 6-month window. It's a lot narrower. I suppose no one knows everything about everyone, even including us.

Dr. Simon: And this is a one-time service benefit, so I would imagine that we would probably consider having a unit of service edit of one for this service.

Dr. McAneny: So what happens to the second doctor?

Dr. Simon: Well, I mean their, I think that one would then have to assume that the patient knowingly develops into a fraudulent relationship with the second physician. Because one, this is a very comprehensive examination, so I'm sure that there would be adequate dialog with the physician to the patient to make them aware that he or she is receiving a Welcome to Medicare physical examination, such that if the patient presents to a second physician, there would have to be some assumption that the patient would be able to express to the new physician that he or she has received this benefit.

Dr. Salive: Some of the benefit of getting that plan at the end is that it can be identified as such. So I think not everyone keeps all their pieces of paper they get at the doctors.

Dr. Rapp: Dr. O'Shea is next, then Dr. Urata, then Dr. Azocar.

Dr. O'Shea: I think we applaud that CMS is trying to venture further and further into preventive care. That's the good part about this. But I see it as more work for the physician, especially my front office. Every time I've got a new Medicare person coming in, they're going to have to say, have you had your Welcome to Medicare and I'm going to get what? I know [?] they're going to say, what? And so what I'm going to ask is that, please don't suppose that the physician has to do all the educa—our part is the education of the medical side, but your part is the education of what their benefits are, so this is going to have to be really well advertised, well

promoted. And I really do truly believe that the 6-month limitation is just too short in the medical industry. That six months goes by too fast and right now I've got my pensions on kind of an annual kind of schema, and if they've just had their physical by their Blue Cross Blue Shield, at 40, 64 in 9 months. Why do I want to see them again 3 months later, as their Welcome to—so I think actually you're spending more, by having that limitation even though it might not seem it. And yes, and do you have Medicare Part B. And again, I would ask that CMS make sure that again you educate, even though you do it all the time, but redundancy or repetition is what really will sink it in because this is Medicare Part B [?] go out there, Welcome to Medicare. And my patients [?] I have Medicare, I want the Welcome. Do you have Part B? And so I need for you guys to do some education. I would make just a recommendation that we increase it to one year, or if it truly is that want to have good preventative care, and it's not just a line item that 6 months is all we're going to fund it for, I really think a full year is more how people have thought about going in for their preventive or their annual care and I don't think we have to reteach them any thing different than that. I would make a recommendation if this is the time to do it—

Dr. Rapp: Is that statutory?

Dr. Salive: That's statutory.

Dr. O'Shea: Oh, you can't do it.

[chatter]

Dr. O'Shea: Then that's my feedback. You guys, great, but you're putting more work on my front desk, that we've got to educate patients, is it Medicare A, Medicare B, have you had this done? It doesn't just happen when they're seeing me, it's a lot more stuff for my front office, so my plea would be to educate them educate them, please, and how do I find that out? When you give them, if the clock starts on January 1st, because they have enrolled, what if they don't call my office? Am I going to get information on my patients from you, Dr. O'Shea, Sophie has joined Medicare B, call her. Or are you going to call her and say, call Dr. O'Shea?

Dr. Salive: We haven't set that up.

Dr. Gustafson: Thank you for that feedback.

Dr. Rapp: Dr. Urata?

Dr. Urata: I was just going to echo what Dr. O'Shea did, and the other thing is, I get past medical records from previous physicians if the patient allows me to, so I would be able to get to know, to address Dr. McAneny's question about what if somebody else already did it. That's how I would know is by getting past medical history and actual records from previous physician. So I don't think that's an issue. I think that the extra work that my front office would have to do because of this new program is something I'm willing to bear because I think this is a big step forward in the health care of the elderly.

Dr. Azocar: You first, your initial question, on how to encourage patient and physicians to implement these new physical exam, maybe from the part of the patient, when they become eligible, for the Part B, and you probably do that already, give them some kind of information, and if possible some kind of an ID that they can take to the physician, to his primary care, because we're talking basically about primary care, that he can know and know that he should do it. That may be one way to inform the person. On the physician side, I wouldn't say independently to the physician, but I will say that you may join forces with some of these organizations, such as Preventive Medicine, or AMA, sort of to approach physicians and let them know, maybe by joining forces with them, it would be more cost effective and more to address this issue and make physicians aware. One of the concerns about increasing the load for the physicians, I think that you may consider also to have some kind of format, we're physician like, where you just grab things, where you have things checked, for example. And by the way, this might be a good opportunity for you to join forces with the previous speaker, Dr. Rollow, who is designing this kind of electronic thing, where you can bring this format for the initial physical exam, and you can bring—

Dr. Salive: We did discuss that with him. Didn't get very far.

Dr. Castellanos: I live in Florida and one of the concerns I have is that our population doubles or triples in the wintertime and it's the Medicare age group. And these patients are not going to get an appointment within 6 months if they're in Florida. I have a hard enough time getting them into a doctor's office if they have chest pain. So I think the work force is really going to be a difficult situation. My second point is, they're being seen initially for a preventive physical exam. If you see them and find something, you see them back. Is that going to be a follow-up visit, or is that going to be another primary visit scheduled for evaluation and treatment. And my third point is, again, we have a mandate by Congress, funded perhaps adequately, perhaps not adequately, good risk of being treating the SGR cap, and here, we are as physicians again going to be financially at risk for this mandate. And I have a lot of concerns about the finances on this.

Dr. Rapp: Mr. Hartstein is going to return for an encore appearance. [laughter]

Dr. Hartstein: You mentioned my favorite subject. The sustainable growth rate. I know Dr. McAneny had mentioned it before. Just for clarification, we have an obligation by law to adjust the SGR for all new laws and regulations that have the effect of increasing expenditures for physician services. The provisions that Marcel talked about, the Welcome to Medicare visit, the cardiovascular screening benefit, the diabetes screening benefit are all the types of services that would be included in the SGR. And we have made an adjustment to the SGR for them. There may be some concern that the adjustment that we made was too small. Or not enough. But we have an obligation under the law to go back and revise those estimates once we've had some experience with the benefit. So our actuary fully intends to look back, after 2005, and look at utilization of all three of these new preventive benefits, adjust the SGR accordingly so physicians will not have to pay if our estimates, if utilization is higher than we anticipated, or lower than we anticipated, it will neither benefit nor penalize physicians. Just by way of anecdote, just because, not that I'm fully aware of all of the efforts that our beneficiary education folks are doing, but we do have a Center for Beneficiary Choices, that does get involved with educating beneficiaries on new

benefits. I happen to be responsible for my mother-in-law's Medicare, so I get a lot of the mailings that come to our house on her behalf. And maybe I look at it more closely than many Medicare beneficiaries do because of my occupation, but I do note that at the beginning of the Medicare handbook, there's a nice letter from Secretary Thompson and from Dr. McClellan, and it does point out many of the changes that are happening in Medicare over the year, and in throughout the handbook there is a lot of very good information on the types of benefits, preventive and otherwise that are available to Medicare beneficiaries.

Dr. Rapp: Thank you. Just out of curiosity, do you have an overall amount of money that this new benefit costs per year?

Dr. Hartstein: The actuary made an estimate for purposes of the SGR, I believe they were estimating at about $40 million for the first year, and I think some of the reason the estimate was there it was, was that some of the concerns that were raised here, about whether the services are the kinds of services that beneficiaries are currently receiving, that it's subject to deductible and co-insurance, the six-month eligibility, but again, there's going to be a look back to evaluate the cost of it once we've had some experience with it.

Dr. Rapp: OK. Thank you. Appreciate that. Are there any formal recommendations we'd like to make pertaining to this subject at this point? Do you want to state what you. . .

Dr. O'Shea: All that I wanted to do was change the timeline—

Dr. Rapp: Well, you can't do that, but how about that widely advertise the nature of the benefit and the rule of limitation and so forth?

Dr. O'Shea: PPAC would recommend that CMS review and strongly document and otherwise widely advertise the new Welcome to Medicare benefit to new Part B beneficiaries, and the limitations and rules pertaining thereof. Thanks Michael.

Dr. Rapp: She's going to work on it a second. Do we have—were you going to say something about the hearing benefit?

Dr. Gaughan: I would just, I don't know if it's a recommendation. But I would change the word hearing impairment. If you'd like me to make that as an official recommendation, I'd be happy to. I think it's just politically correct, and I'm sure you want to be politically correct. So I don't think there's a recommendation.

Dr. Gustafson: We don't want to offend anyone with our policies anymore than we're forced to of course by the law. The question of the benefits that may be triggered by the [?] desirability for benefits that might include the beneficial—I think there might be a benefit category question on the hearing testing. Which and benefit categories are basically statutory. So we'll take that back and look at it. But in so far as it is a coverage question, it would be open for consideration by the coverage folks. If it's a benefit category determination derived from the way the statute is set up—

Dr. Gaughan: [?] is covered, hearing loss is not. Currently.

Dr. Gustafson: We'll give it a look.

Dr. Gaughan: Thank you.

Dr. O'Shea: Silly question. When they get Medicare Part A, do they get a certain card, they get a different Card when they have Medicare Part A and B? Do you date it? Enrolled, date?

[chatter]

Dr. Rapp: OK, Dana, can you read back Dr. O'Shea's motion?

Ms. Trevas: PPAC recommends CMS pursue multiple avenues to educate beneficiaries about the new Welcome to Medicare benefit to new Part B beneficiaries, and it's limitations and rules.

Dr. Rapp: That was beautifully crafted!

Ms. Trevas: I just wanted to ask Dr. O'Shea, when you said document, did you mean something that I missed?

Dr. Rapp: No, she just means put it in writing. OK.

Dr. Simon: One additional point, during the time that a Welcome to Medicare physical examination is performed, if other screening tests are performed during that benefit, those screening tests are separately payable. So the screening mammography, the pelvic examination, the glaucoma exam, the colorectal screening exam, etc. All of the other—

Dr. Gustafson: The stuff we were previously paying for.

Dr. Simon: The stuff we were previously paying for are separately billable in the same setting. Yes.

Dr. Rapp: OK, so any discussion on Dr. O'Shea's motion? If not, all in favor?

[Ays]

Dr. Rapp: All opposed? That motion carries. OK, anything else on this subject matter? Dr. McAneny?

Dr. McAneny: I think this is a great opportunity not only to improve what we're doing in terms of prevention but also to get some reasonable data on the availability of some of the screening tests, in particular, mammography, colonoscopy, all those. We've been looking at that locally and trying to estimate what our local work force is if we wanted to do say colonoscopy in every patient over 50 in New Mexico and discover we don't have nearly the number of people to do it. And there is no data anywhere. No one has any data on how many gastroenterologists or primary care physicians who are trained in doing colonoscopy or sigmeundoscopy would be available. So this would be a great opportunity to get some of that public health type data.

Dr. Rapp: OK, if there's nothing else, we will take a 15 minute break. I believe there are some cookies over there in the corner for those that didn't get enough to eat for lunch.

K. BREAK

Dr. Rapp: To the extent we'll have a couple additions for the Medicare Coverage process, but to the extent that you have some pending recommendations, I'd like to get them out on the table now for prior items to help our reporter get things together. So I know Dr. McAneny has one.

Dr. McAneny: Actually, two. I can read them slowly. PPAC recommends that since CMS has already compiled a list of the prices of drugs in order to determine ASP, that the list be available on the website so that physicians can purchase drugs under ASP.

Dr. Rapp: Is there a second to that?

[seconds]

[chatter]

Dr. Gustafson: The only information we have already. And if you want us to do more, let's be clear about what it is you'd like us to do.

Dr. McAneny: . . .the prices of drugs by manufacturers, because what I'm trying to do here is since ASP is going to be an average, and what you have available locally may not be under that average, that and since CMS already had to get prices from all these manufacturers in order to come up with ASP should be, it would be very helpful to the physician community, not just oncology, but everybody who's purchasing drugs and wants to be under average selling price to be able to know who they can purchase these drugs from. The drug companies won't like that but I figure drug companies are sort of, they're doing fine under this. I don't weep tears for them.

Dr. Rapp: OK. Could we read the motion back?

Ms. Trevas: [off mike] CMS has already compiled a list of drugs by manufacturer to determine ASP, PPAC recommends the list be published on the website so physicians can use that information to purchase drugs.

Dr. Rapp: OK, there was a second, I believe. Is there discussion on that? All in favor?

[Ays]

Dr. Rapp: All opposed? That motion carries. You had one other?

Dr. McAneny: I do. PPAC recommends that CMS and the Office of the Actuary compare and contrast the factors in the MEI and the market basket to explain why the same index cannot be used for physicians and hospitals.

Dr. Rapp: Is there a second to that?

[second]

Dr. McAneny: May I speak to it?

Dr. Rapp: Yes.

Dr. McAneny: We heard earlier in the presentation under the Hospital Outpatient Prospective Payment System that all of the hospitals were getting 4% raises here and 6% raise there and 3% raise somewhere else and I think a lot of the differences we use as Medicare economic index, that calculates the amount that we get, whereas they seem to have this market basket. And when I try to read about the market basket in terms of the increases in prices that they're getting, a lot of it to me looks like it's coming from that. Now I'm not an accountant or an actuary, so I would like to hear from those folks, what goes on with the market basket. It seems to me that we're competing for the same widgets for the same supplies for the same pool of educated labor, nurses and techs, etc., as the hospitals are, yet we have our practice expense determined in a different manner. And I would like to really have a point by point description about why the market basket is appropriate for hospitals, but not appropriate for physicians and vice versa.

Dr. Rapp: Any comments or discussion on that?

Dr. Gustafson: I would just observe that it sounds like your concern has to do with a broader question than simply the nature of these two indices. To the question of how the Physician Fee Schedule versus the Outpatient Prospective Payment System are updated. I mean there's nothing comparable to the SGR for outpatient. But we could certainly provide a discussion description, written or otherwise of what those differences are, both in terms of the input measures that are being looked at, how they move into the indexes and how that results in differences in the payments rates at the end of the day.

Dr. Rapp: Would that be sufficient rather than the recommendation?

Dr. McAneny: I'd like to have the formal recommendation out as well, but I think that clearly as we look at the SGR and what it's going to do to all of physicians starting in 2006, that

they're going to have to be some changes made in this system. And I think it's reasonable for us to start with looking at what the alternative systems might be. Using a market basket approach as opposed to I would welcome the addition of the MEI and the SGR in there so that you can include all of those things you were discussing.

Dr. Rapp: OK, read the motion back, please?

Ms. Trevas: PPAC recommends that CMS and the Office of Actuary compare and contrast the factors in the MEI and the market basket to explain why the same index cannot be used for physicians and hospitals.

Dr. Rapp: Further discussion on that? All in favor?

[Ays]

Dr. Rapp: All opposed? That motion carries. Is there any other motions from the prior items? Yes, Dr. Castellanos?

Dr. Castellanos: The one-year demonstration project, I would like to participate, a physician must 1. treat a cancer patient, provide chemo therapy by push, infusion, intravesticle application, subcutaneous intramuscular and surgical implants. They must also report the assessment of the patient's pain, nausea, fatigue on a scale of one to four. The reason I'm doing this is if it's CMS's goal to collect this data, I think it's best to collect it from as many cancer patients as you can, as many physicians as you can, and from as many specialists who are treating cancer patients. And this is their primary goal for doing this one year demonstration project. Let's make it a good project.

Dr. Rapp: So this demonstration project—is this subject to revision, just out of curiosity? Is it part of the rule that modifiable.

Dr. Gustafson: . . . as a practical matter, it's unlikely the administration will consider revisions in it of any significant nature.

Dr. Castellanos: I understand that, but there are reasons why you make recommendations sometimes.

Dr. Rapp: OK, so I didn't hear the part about PPAC recommends what?

Dr. Castellanos: It's based on the one-year demonstration project, PPAC recommends to participate in the one-year demonstration project, a physician must—you may want to read that back. I had given it to you.

Dr. Rapp: So you're asking to expand the demonstration project to include what?

Dr. Castellanos: Provide chemotherapy by push, infusion, intravesical application, that's within the bladder,

Dr. Rapp: But you're asking to expand it to some sub cu IM and intravesical,

Dr. Castellanos: and surgical implants. OK, can you read it to us, Dana?

Ms. Trevas: PPAC recommends that CMS expand the criteria for participation in the one-year demonstration project on cancer patients to include in addition to push and infusion chemotherapy, subcutaneous, intramuscular, intravesical applications, and surgical implants.

Dr. Rapp: OK. Has that been seconded? Do we have a—that would presumably expand this beyond $300 million? Right? Potentially a lot. Just an observation. OK. Any further discussion? All in favor of that motion?

[Ays]

Dr. Rapp: Raise your hands. One, two, three, four, five, six, seven –OK, looks like that carries. All opposed? OK. That motion carries. Anything else on the subject matter that we've covered previously? OK, that takes care of that. So you've already got the recommendations up to these last two items, and we'll now move on to the last item on the agenda, the Medicare—both the lights go on and the bell starts ringing—I must have said something! [laughter] Did I get $300 billion?

Dr. Bergeron: Could be! Are you nauseated? Are you vomiting? [laughter]

Dr. Rapp: I'm not nauseated and I'm feeling well. And I'm not tired at all. OK, here we go. On the Medicare Coverage Process, Dr. Salive is going to discuss that as his next presentation.

Dr. Salive: Thank you. I just want to provide kind of an update on the coverage process and get your thoughts on a couple of things on first, if you have any suggestions or recommendations about engaging physicians in the coverage process, and I think also, we'll have some discussion perhaps about the level of evidence that we use for paying for deciding on coverage for services. So we're kind of pushing the envelope there and would like to get some input on that.

The authority for the coverage is from the Social Security Act and it's fairly lean and ;mean and it just says that coverage is limited to items and services found reasonable and necessary for treatment of illness or injury. And that has been there for the duration, I guess. And as I said in the last talk, this is where prevention does not sit treatment of illness—and those items are listed one by one.

What is reasonable? This was out in my back yard a couple weeks ago.

Well we apply reasonable and necessary based upon adequate evidence to conclude that the items improves net health outcomes and in generalizable to the Medicare population. So that's an evidence based medicine approach to coverage. And we use the hierarchy of evidence to reduce compounding fines.

So what is the coverage process? This was Sean's kid. Well, we receive requests for coverage periodically and I just want to discuss the provisions we made mainly to the timeline based on the Medicare Modernization Act, and so we were open to preliminary meetings with anybody. I'm up in the upper left corner, which is usually helpful in terms of going through some of the preliminary issues that may come up. Certainly, we have to understand the benefit category issues before we can open a national coverage decision, so that we can only cover things where there is a benefit category and we work with our colleagues in CMM to understand that. When we get a request, at this point when we open the request, the time clock starts ticking. We used to be able to creatively manage the clock, like those coaches do I guess, although not so well here in DC. But now the clock is very rigid, so when we open a coverage decision, we have either 6 or 9

months to issue a draft decision memo. And the difference here is if we do an internal assessment of the evidence, we have 6 months. If we use our Medicare Coverage Advisory Committee or engage in outside technology assessment, which we do through the Agency for Healthcare Research and Quality, then we have 9 months to complete that decision and post a draft, which we now post everything out on our coverage website. And so at that time, we open the draft for 30 days of public comment and we then have 2 more months after that to digest the comments issue a final decision, and at that same time, the implementation will take place. So it used to also be that there was more time would pass after a final coverage decision was issued, before the implementation would take place. We really don't have that kind of luxury anymore. So we're now following this for about, since January 1, we've been following this process and we're following the timelines very closely on it. So any time that we issue a decision, of course, it can be reopened again for reconsideration based upon either new evidence, or some allegation that we misrepresented the evidence. Those are the two avenues basically for a reconsideration, and then the process can start again. Individual cases are now appealable to the Departmental Appeals Board.

So that's the coverage process. What I wanted to talk about just briefly is that we are now pushing the envelope a little bit on evidence-based decision making and trying to cover a few more things where the level of evidence is a little bit lower and try to get early coverage with an agreement that people will collect data to understand the evidence of effectiveness down the line. So specific examples that you may have heard about recent coverage issues in this area include the PET scan for Alzheimers disease, which was issued in September, and some recent draft decisions that have been posted on PET scans for several types of cancer, and as well, the announcement about colorectal cancer drug trials, which involves 9 NCI trials that investigate certain off-label uses for specific drugs. And a final one is a more of a registry approach to collect proposing to collect continuing data on implantable cardiac defibrillators to understand the effectiveness of those devices in practice going forward. So we've been looking at some coverage

requests where the evidence was not up to our standard and trying to come up with sort of a middle ground, and saying we will collect data on the effectiveness and provide some coverage in that formal setting of data collection with the understanding that we could use that evidence subsequently to understand better how the technology works.

So I wanted to get your input on involvement in the coverage process or on that level of evidence.

Dr. Rapp: Dr. Urata, Dr. Powers, Dr. Johnson?

Dr. Urata: Are you part of, you're part of CMS that pays the bills, and you're going to do studies to determine if you should pay the bill? Isn't that bias? Shouldn't a different entity—

Dr. Salive: We're not doing the studies. I guess that's a good point. We are in fact trying to engage others to do those studies. The coverage group of CMS deals with these kind of coverage policy questions. We do work with the payment folks on payment. The one trial, the 9 trials for colorectal cancer, actually NCI is conducting those trials. The PET scans for cancers were exploring how to involve NCI with that and they would probably take the lead. So it's not our intention for CMS to engage internally and do that kind of research.

Dr. Powers: Is there MedLearn on this [?] process? The reason I ask that is I kind of backed into the website one day and I got myself put on the email list that comes out on these coverage decisions, which is really nice. And it keeps you up to date, and then, what I did because it wasn't always something in my area, but it might be something in neurology, I just had my academy get on that mailing list so that they could take care of that and get with the appropriate people. And the Alzheimers thing went through well for the PET scanning. I realize it was a lot of work and a lot of questions, but it went through well. But I don't think a lot of people know about that. I'm assuming specialty societies know. I don't know if everyone knows. The second part of my question though is for little things, like getting, there was just an oversight, if I'm not mistaken, there's an NCD for coverage on B-12 testing. And neuropathy was left off that. And it just seems like a lot of work just to get that put on when, to go through this 6 or 9 month.

Dr. Salive: I don't think we have a MedLearn matters on coverage process. That's a good idea we'll take back. One thing we are doing is to try to issue guidance documents on the coverage process. That all came out of the Medicare Modernization Act. And so we have started to develop guidance and to take input on how we should do guidance documents so that people who want to submit coverage can understand the process a little bit better. And so probably in conjunction with that, we could do some sort of MedLearn article. With respect to the second part, the testing NCDs are a much more streamlined than I presented and to add a code or diagnosis that was left off, as you're saying, is a much shorter process. It can be done. I think it takes a matter of a month.

Dr. Powers: So I can email you and you can tell me how to do?

Dr. Salive: Yeah, I'll tell you who to get in touch with.

Dr. Johnson: Having been a part of the Medicare Coverage Advisory Committee when we looked at the PET scan coverage on cancer and Alzheimers, I applaud what you have done there with regard to the Alzheimers and the coverage with the PET scan. I think it's a move in the right direction. When some of the coverage was brought before, back in 2000, 2001, in that process, some on the coverage had those concerns on the panel, and it's nice to see that you now have moved into some of the coverage where some of the data can be collected on some of these new technologies to make a better coverage policy that may be more broad of benefit. Very good.

Dr. Leggett: I just had a comment on the evidence-based approach, which I think is absolutely critical to the basic practice of medicine, which is having levels of evidence to support whatever your therapeutic intervention may or may not be. With that said, I think that as you pursue this issue, one question I would have, for instance, with the defibrillator issue, why would you not utilize the existing committee that already exists with the ACCA [?] Rights published guidelines on these issues? Why would you not use that as your barometer? Because, to Dr. Urata's point, that is an uninfluenced body. It's a third party. It's independent. These are individuals who are presumably not purchased by any particular entity and they are well

respected. I mean these guidelines form the basis by which we practice everyday. Takes huge swings out of practice patterns in the country. So I think when considering something as important as this defibrillator issue, I really don't see a point in establishing another body to address this. Why not use the already respected bodies that are sub-specialty based that are in fact sort of authenticated by the individuals in the specialty who actually revere these opinions quite substantially?

Dr. Salive: Well, that's a good point. I think I agree with what you said. We did basically just that to some extent. But I think we went a little bit farther. And I'll just say why. We do look at those guidelines statements as part of our evidence review and we look at the methods that they use to develop the guidelines. So that when they say something at the College of Cardiology is 1A or something based on clinical trials and that's on their guideline, we make note of that and we do also look back at the trials themselves. But in fact the evidence-based guideline is practically one of the highest levels of evidence we have. Only think higher really is kind of a META analysis.

Dr. Leggett: It's actually less.

Dr. Salive: It's kind of hard to really differentiate it, sometimes.

Dr. Leggett: It's pretty easy actually.

Dr. Salive: In terms of our levels. To get to your point about why do we do our thing. I guess that the College of Cardiology says they want to wait six months until after a trial is published before they will change their guidelines. So we have been trying to respond to that ourselves and trying to be a little bit proactive on defibrillators and trying to change coverage based on things a little bit quicker than that, and so that's why.

Dr. Leggett: Let me just respond to that because I think that part of your proactivity is really not generated by the lag time it takes to authenticate more than the guidelines are [?] but there's really pressure from private industry that wants you to pay for defibrillator usage and they keep pressuring you guys to come up with an answer as to whether or not this is indeed the

correct thing to do. And I think you really have to eliminate them from the picture because their interests are clearly biased, and they're not necessarily in their own privately company-funded studies that create this interim data that is not necessarily what the guidelines are based on is often times in review, frankly not the way to go. So I think historically what's happened with the guidelines is that the waiting period is appropriate because it actually assesses the information in totality. And then the updates come. I mean the guidelines may be published every four years but in the interim there are updates that come out all the time, and I think that that standard has not failed us in the past and to try to reinvent what actually may be a less qualitative way to do it is likely not [?].

Dr. Salive: I think I agree with what you said.

Dr. McAneny: A suggestion then a question. The suggestion is you already had a CAC system in place, the carrier advisor committees for local LCDs, not LMRPs anymore? And so it seems to me that that ought to be an integration and a fast track into the national coverage decisions if something goes through one of the CAC processes, that that ought to be able to slide into your diagram of how the national coverage decisions are made.

And the second is a question. On your clinical trials that your setting up for things like PET and Alzheimers. One of the concerns that we've had is that if people sign up for a Medicare Advantage Plan, thinking that they're going to have the benefits of that plan and just having copay etc., but then they sign up for a clinical trial, they suddenly revert back to standard fee-for-service Medicare, but they've given up any sort of Medigap. So therefore, any person who's on a Medicare Advantage, if they sign up for the clinical trial for the PET scan will suddenly find themselves responsible for 20% of the cost of that particular PET scan. So I'm wondering if you're going to—does that make sense? Not entirely? That's how the Medicare Advantage part is written. That if somebody is on a clinical trial, they revert back to fee-for-service Medicare, but when they sign up for Medicare Advantage, they've given up their Medigap insurance. So if you put somebody who's on Medicare Advantage for a clinical trial, you're going to tell them that

they have to then pay 20% of the cost of it because Medicare fee-for-service only covers 80%. So what's going to happen? It's confusing you. Imagine if you had Alzheimers. [laughter] All these patients are going to suddenly discover that they're responsible for 20% of that unless you put some sort of a process in your clinical trial that says this includes Medicare Advantage patients since it is a Medicare clinical trial, it seems to me that might be possible.

Dr. Salive: We can explore that. I don't know the answer to that. I think it's a good point. We'll take it back.

Dr. Rapp: OK. Anything else? If not, thank you very much for your presentation. Are there any recommendations with reference to the subject matter we've just covered? If not, are there any other items? Yes, Dr. Powers?

Dr. Powers: PPAC recommends that CMS provide the discussion materials for agenda items at least three weeks prior to the PPAC meeting to allow for preparation and self-education by PPAC members.

[seconds]

Dr. Rapp: Could we read that back, please?

Ms. Trevas: PPAC recommends that CMS provide the discussion materials for agenda items at least three weeks prior to the PPAC meeting to allow for preparation and self-education by PPAC members.

Dr. Rapp: Any discussion on that?

Dr. Gaughan: Well, I think it's vital to be able to read this ahead of time. And I did not get very much information this time and I was a little disappointed because I had nothing to read on the plane but a novel, so I certainly would appreciate it.

Dr. McAneny: What? 800 pages of Medicare Fee-for-Service publication! [laughter]

Dr. Rapp: I'm sure that the staff really doesn't have any objection to this except it's, of course, a gargantuan job to try to get this material together so I think, I just want to say that—

Dr. McAneny: They could just send us links of things that are pertinent.

Dr. Rapp: And this particular meeting was in the midst of many other things. So perhaps it wasn't as early as in other meetings, but in any event, yes?

Dr. Castellanos: Along those same lines, do we have any dates for next year's meetings?

Dr. Rapp: Well, we haven't finished with this motion.

Dr. O'Shea: One comment also. I think that some things may be sensitive. I think that we've heard that in comment that some things truly aren't in their form, so if they're listed as draft, of course all those things can be kept by PPAC members until things are decided here. I think that comment was made that some things aren't really truly decided til the moment they come here. But we've like to have more grist to chew on before we get here, if it's in a draft form, we accept that.

Dr. Rapp: All in favor?

[Ays]

Dr. Rapp: Anybody opposed? All right that motion carries. Anything else? If not, we can take a—yeah, we can discuss that. We can let our reporter deal with the motions. Did you want to print those out Dana?

Dana off mike

Dr. Rapp: We have no verbal testimony that I know of. Right? So let's see, what time is it? We can easily take a break And then we can discuss, and go off the record and talk about schedule for next year.

Dr. Urata: Can I make a request, first?

Dr. Rapp: Yeah.

Dr. Urata: I don't know if this would go on the record or not. It's just a request for a report of the status of Medicare payment for cardiac rehab in patients with acute coronary syndrome who've been treated with angioplasty or bypass and thereby preventing a heart attack, since there is no heart attack, Medicare does not cover cardiac rehab, despite the fact they still have all the risk factors and may have had some slight injury. And—

Dr. Rapp: I'm not sure I follow that. You're requesting what?

Dr. Urata: Well, I'm requesting a report on the status of Medicare payment. Apparently CMS is looking at cardiac rehab because there's new diseases associated with the heart, including acute coronary syndrome, which used to be called unstable angina, and cardiac rehab in the past has been for treatment and rehab for patients with a heart attack. Now that we get these patients and do angioplasty or bypass on them, we are able in many cases to prevent actual injury to the heart. And it's beneficial to have these patients go through cardiac rehab at least for the educational component to help them to prevent future second heart attacks, or secondary acute events, engaging them in prevention, low cholesterol, diabetes control, blood pressure control, weight loss and increase their activities and take their medications. And cardiac rehab has been shown to promote this in a very positive way. But I've had one patient come back after having unstable angina and having successful treatment, but I couldn't get them into cardiac rehab and it's my understanding that this is happening all across the country because we've sort of eliminated the actual heart attack, Medicare will not allow them to go through with cardiac rehab and I think that's something that ought to be done.

Dr. Rapp: So there's a coverage issue with regard to rehab for people who have sustained acute coronary syndrome without an actual myocardial infarction?

Dr. Urata: Right, and because of that fact, that they haven't had the injury, they're not under the current codes, they're not acceptable for rehab.

Dr. Rapp: OK, can we just note that as a possible—

Dr. Simon: We can note that as a point of information for the Council. Currently the coverage group is looking at the spectrum of services covered under the umbrella of cardiac rehab. And have been awaiting a report from the Inspector General's office in order to continue and finalize the work toward a national coverage determination on this whole process. So I think it would, it's still a process that's in a state of evolution at this point until the coverage group proceeds with recommendations from the Inspector General's Office.

Dr. McAneny: For future discussions as well, I would like to hear about the upcoming changes in the conditions of participation for hospitals that we're hearing more and more about that and how the autonomy of the medical staff may be preserved or whether or not the conditions will turn that over to Human Resources departments but, and that may be something you want to ship us a bunch of stuff to read on ahead of time because I at least require a fair amount of education on how that works. But I think that will affect a lot of physicians across the country.

Dr. Rapp: As far as the next meeting date, have we, do we have such a thing? March? But we don't have a specific date? Like early March? It's usually February having to do with the Physician Payment Fee Schedule, so we've had it at the end—so we've pushed it up from March. I think previously. The comment period for the Fee Schedule.

Dr. Simon: The Proposed Rule will be, usually it's not published until June so there would still be adequate time to make the request and recommendations.

Dr. Rapp: So we don't have a specific date yet?

Dr. Simon: No.

Dr. Rapp: But in any event, I don't think we'll take a break because I think people want to wind it up. I think if it's OK, what we've done, why don't we look at the recommendations that we have so far in writing and let me see if there's any editorial changes on that. And then with regard to the others, hopefully you'll leave it to me to make any editorial corrections that are necessary. But I think Dana got those done because she was dealing with those in writing for the most part. Are there any corrections on these? If not, let's see, do we have any closing—oh.

Dr. ??: I just have a verbal. On the Agenda Item C-1? Let's change that before the next meeting should be before each PPAC meeting.

Dr. Rapp: I thought that's what you meant.

Dr. ??: It's what I meant. It isn't what I said.

Dr. Rapp: Anything else on the recommendations are provided to you? If not, Dr. Gustafson, would you like to say any closing remarks?

Dr. Gustafson: After my inspiring opening remarks. I actually just have a question for the members of the Council. Herb Kuhn had very deliberately set forth the tasks for folks coming to present to you. And we've been trying to structure the agenda to some extent around the notion that we would present you with explicit questions wherever we could think of some, or wherever it was pertinent, and you have noticed that I think, in some of the presentations that we came with today. Sort of laying those out up front, issues that we thought that you might profitably find on and where we might certainly value your input. And I guess I would just seek any reaction Council members have as to whether that is an effective thing for us to be doing; should we be doing more of it, less of it? Obviously sending them out farther in advance, we got that message. But is that, just a little fast evaluation here—is this good stuff? Do you want more? Want it like that?

Dr. McAneny: It is good stuff. It helps us to be more proactive and get some input earlier in the decision making process instead of waiting in reacting to things already done and then saying, Gee, it would have been nice if you'd done this instead.

Dr. O'Shea: It gives us an idea of their perspective on what they feel we have comments on, and sometimes that's right on and sometimes that's not really where we have concern about it at all. So I think it's very educational. And again, it's just instant feedback.

Dr. Gustafson: We found it educational. Discovered the things you were really interested in talking about and the things less so.

Dr. Castellanos: It gives us the opportunities to go into our communities and ask advice from other people too, besides ourselves. I think that's really good.

Dr. Rapp: I think it was helpful and I would encourage you to do more of it. Anything else?

Dr. Gustafson: No, thank you all for coming. You gave us a lot to think about and work on and we'll do that and [inaudible] specific questions that occur to you on the plane home, you know who to get through. We want to be accessible to you and answer questions as best we can.

Dr. Rapp: For our part, I want to thank you for spending the whole day with us, as I've mentioned before. I know there's only so many days in the year, and to give an entire day to the work of the Council demonstrates the importance that you and the Agency places on it. So thank you for being here. Dr. Leggett?

Dr. Leggett: Is there any way to correlate the recommendations being made with you know, what's done with them and percentage relationship between recommendations and changes? We would intuitively like to know that our recommendations have some impact on someone.

Dr. Rapp: You could do an article for Jamma.

Dr. Leggett: Seriously, I think it has relevant interest on the part of people who are on the Panel.

Dr. Gustafson: You're saying this is something scorecardish. You recommend on tender for items and the Agency said yes on 8, and no on 2? Or something like that?

Dr. Leggett: Well, I guess I'm more interested, when you compile this list, there might be 20 or 30 things on it and frankly, I guess what interests me is are these just sort of static things that go out to the environment that have no impact on anything, or can you correlate some of these recommendations with actually how they are ingested by CMS and do they have any affect on changes, policy, etc.?

Dr. Gustafson: Let's give some consideration on how we might best incorporate some feedback of that sort.

Dr. McAneny: Do we need to make formal requests for the cardiac rehab that Dr. Urata mentioned and the hospital conditions of participations to have those as an agenda item, or is it sufficient that we just sort of threw them out there and you heard them.

Dr. Gustafson: I think we've taken note of them, and we may need to have some further discussion to make sure we've got all of the details here. So we will report back to you on those either in the sort of formal report that Ken was doing and we heard the messages there, we want

to be able to provide that information more fully to you, or in more specific instances it may be something that a quicker report by email in the interim might be suitable for us.

Dr. Rapp: I would also like to just note that I understand Jack Emry is going to be retiring soon, and he's definitely been in a lot more PPAC meetings than I have, and he's rarely missed one and is very helpful to the PPAC members in giving information and bringing testimony from the American Medical Association that has a lot of interest in our work, so I think it's appropriate at this time to acknowledge his many years of service in behalf of physicians and appreciate his interaction with PPAC. [applause] And there's another person that's been with PPAC even longer than Jack, or at least as long, and that's John Lanigan. And he started with PPAC in the beginning, right? 1991, so he's, it's always good to have staff members that can give you the oral history of everything that's happened, so he can basically tell you and comment on virtually every PPAC member. Certainly every chair that's been here, and so he doesn't talk too much about all of his things that he's done. But he's done plenty in behalf of the Council and behalf of physicians and behalf of our government running the Medicare Program. So I want to acknowledge that and thank you. [applause] Yes.

Dr. Castellanos: I wasn't going to do anything, because John asked me not to. But since you brought it up, I have one more resolution. May I read this? Whereas John Lanigan has provided PPAC with logistical assistance since its inception; whereas Mr. Lanigan has made every effort to be helpful to each individual PPAC member; whereas John has worked long hours, weekends to make each PPAC meeting successful; whereas Mr. Lanigan has performed his duties with competence and diligence; where John has treated each PPAC member with deference and kindness; where John Lanigan has exemplified all that is good and worthwhile about federal service; where John Lanigan is about to retire from government services, this may be his last PPAC meeting, be it resolved that members of PPAC thank John for his dedicated service to the Council, bring his excellent work to the attention of CMS Management and we all wish him good health and a well deserved and long and happy retirement. [applause]

Dr. Rapp: In so far as you're considering [laughter] I think we'll accept that as acclimation. Any other items that the Council wants to bring up? If not, I thank all the members of the public and CMS staff that have come here for the meeting and wish you all Happy Thanksgiving and safe travels home.